

Calendar No. 110

104TH CONGRESS
1ST SESSION

S. 454

[Report No. 104-83]

A BILL

To reform the health care liability system and improve health care quality through the establishment of quality assurance programs, and for other purposes.

May 16 (legislative day, May 15), 1995

Reported with an amendment

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 16 (legislative day, JANUARY 30), 1995

Mr. McCONNELL (for himself, Mr. LIEBERMAN, and Mrs. KASSEBAUM) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

MAY 16 (legislative day, MAY 15), 1995

Reported by Mrs. KASSEBAUM, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To reform the health care liability system and improve health care quality through the establishment of quality assurance programs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
 3 “Health Care Liability Reform and Quality Assurance Act
 4 of 1995”.

5 (b) **TABLE OF CONTENTS.**—The table of contents is
 6 as follows:

Sec. 1. Short title; table of contents.

TITLE I—HEALTH CARE LIABILITY REFORM

Subtitle A—Liability Reform

Sec. 101. Findings and purpose.
 Sec. 102. Definitions.
 Sec. 103. Applicability.
 Sec. 104. Statute of limitations.
 Sec. 105. Reform of punitive damages.
 Sec. 106. Periodic payments.
 Sec. 107. Scope of liability.
 Sec. 108. Mandatory offsets for damages paid by a collateral source.
 Sec. 109. Treatment of attorneys’ fees and other costs.
 Sec. 110. Obstetric cases.
 Sec. 111. State-based alternative dispute resolution mechanisms.
 Sec. 112. Requirement of certificate of merit.

Subtitle B—Biomaterials Access Assurance

Sec. 121. Short title.
 Sec. 122. Findings.
 Sec. 123. Definitions.
 Sec. 124. General requirements; applicability; preemption.
 Sec. 125. Liability of biomaterials suppliers.
 Sec. 126. Procedures for dismissal of civil actions against biomaterials suppliers.

Subtitle C—Applicability

Sec. 131. Applicability.

TITLE II—PROTECTION OF THE HEALTH AND SAFETY OF PATIENTS

Sec. 201. Health care quality assurance program.
 Sec. 202. Risk management programs.
 Sec. 203. National practitioner data bank.

TITLE III—SEVERABILITY

Sec. 301. Severability.

1 **TITLE I—HEALTH CARE**
2 **LIABILITY REFORM**
3 **Subtitle A—Liability Reform**

4 **SEC. 101. FINDINGS AND PURPOSE.**

5 (a) FINDINGS.—Congress finds the following:

6 (1) EFFECT ON HEALTH CARE ACCESS AND
7 COSTS.—That the civil justice system of the United
8 States is a costly and inefficient mechanism for re-
9 solving claims of health care liability and compensat-
10 ing injured patients and that the problems associ-
11 ated with the current system are having an adverse
12 impact on the availability of, and access to, health
13 care services and the cost of health care in this
14 country.

15 (2) EFFECT ON INTERSTATE COMMERCE.—
16 That the health care and insurance industries are
17 industries affecting interstate commerce and the
18 health care liability litigation systems existing
19 throughout the United States affect interstate com-
20 merce by contributing to the high cost of health care
21 and premiums for health care liability insurance pur-
22 chased by participants in the health care system.

23 (3) EFFECT ON FEDERAL SPENDING.—That
24 the health care liability litigation systems existing
25 throughout the United States have a significant ef-

1 fect on the amount, distribution, and use of Federal
2 funds because of—

3 (A) the large number of individuals who
4 receive health care benefits under programs op-
5 erated or financed by the Federal Government;

6 (B) the large number of individuals who
7 benefit because of the exclusion from Federal
8 taxes of the amounts spent to provide them
9 with health insurance benefits; and

10 (C) the large number of health care provid-
11 ers who provide items or services for which the
12 Federal Government makes payments.

13 (b) PURPOSE.—It is the purpose of this Act to imple-
14 ment reasonable, comprehensive, and effective health care
15 liability reform that is designed to—

16 (1) ensure that individuals with meritorious
17 health care injury claims receive fair and adequate
18 compensation, including reasonable non-economic
19 damages;

20 (2) improve the availability of health care serv-
21 ice in cases in which health care liability actions
22 have been shown to be a factor in the decreased
23 availability of services; and

24 (3) improve the fairness and cost-effectiveness
25 of our current health care liability system to resolve

1 disputes over, and provide compensation for, health
 2 care liability by reducing uncertainty and unpredict-
 3 ability in the amount of compensation provided to
 4 injured individuals.

5 **SEC. 102. DEFINITIONS.**

6 As used in this subtitle:

7 (1) CLAIMANT.—The term “claimant” means
 8 any person who commences a health care liability ac-
 9 tion, and any person on whose behalf such an action
 10 is commenced, including the decedent in the case of
 11 an action brought through or on behalf of an estate.

12 (2) CLEAR AND CONVINCING EVIDENCE.—The
 13 term “clear and convincing evidence” is that meas-
 14 ure or degree of proof that will produce in the mind
 15 of the trier of fact a firm belief or conviction as to
 16 the truth of the allegations sought to be established,
 17 except that such measure or degree of proof is more
 18 than that required under preponderance of the evi-
 19 dence, but less than that required for proof beyond
 20 a reasonable doubt.

21 (3) HEALTH CARE LIABILITY ACTION.—The
 22 term “health care liability action” means a civil ac-
 23 tion in a State or Federal court—

24 (A) against a health care provider, health
 25 care professional, or other defendant joined in

1 the action (regardless of the theory of liability
2 on which the action is based) in which the
3 claimant alleges injury related to the provision
4 of, or the failure to provide, health care serv-
5 ices; or

6 (B) against a health care payor, a health
7 maintenance organization, insurance company,
8 or any other individual, organization, or entity
9 that provides payment for health care benefits
10 in which the claimant alleges that injury was
11 caused by the payment for, or the failure to
12 make payment for, health care benefits, except
13 to the extent such actions are subject to the
14 Employee Retirement Income Security Act of
15 1974.

16 (4) HEALTH CARE PROFESSIONAL.—The term
17 “health care professional” means any individual who
18 provides health care services in a State and who is
19 required by Federal or State laws or regulations to
20 be licensed, registered or certified to provide such
21 services or who is certified to provide health care
22 services pursuant to a program of education, train-
23 ing and examination by an accredited institution,
24 professional board, or professional organization.

1 (5) HEALTH CARE PROVIDER.—The term
2 “health care provider” means any organization or
3 institution that is engaged in the delivery of health
4 care items or services in a State and that is required
5 by Federal or State laws or regulations to be li-
6 censed, registered or certified to engage in the deliv-
7 ery of such items or services.

8 (6) HEALTH CARE SERVICES.—The term
9 “health care services” means any services provided
10 by a health care professional or health care provider,
11 or any individual working under the supervision of
12 a health care professional, that relate to the diag-
13 nosis, prevention, or treatment of any disease or im-
14 pairment, or the assessment of the health of human
15 beings.

16 (7) INJURY.—The term “injury” means any ill-
17 ness, disease, or other harm that is the subject of
18 a health care liability action.

19 (8) NONECONOMIC LOSSES.—The term “non-
20 economic losses” means losses for physical and emo-
21 tional pain, suffering, inconvenience, physical im-
22 pairment, mental anguish, disfigurement, loss of en-
23 joyment of life, loss of consortium, and other
24 nonpecuniary losses incurred by an individual with

1 respect to which a health care liability action is
2 brought.

3 ~~(9) PUNITIVE DAMAGES.~~—The term “punitive
4 damages” means damages awarded, for the purpose
5 of punishment or deterrence, and not for compen-
6 satory purposes, against a health care provider,
7 health care organization, or other defendant in a
8 health care liability action. Punitive damages are
9 neither economic nor noneconomic damages.

10 ~~(10) SECRETARY.~~—The term “Secretary”
11 means the Secretary of Health and Human Services.

12 **SEC. 103. APPLICABILITY.**

13 ~~(a) IN GENERAL.~~—Except as provided in subsection
14 ~~(c)~~, this subtitle shall apply with respect to any health care
15 liability action brought in any Federal or State court, ex-
16 cept that this section shall not apply to an action for dam-
17 ages arising from a vaccine-related injury or death to the
18 extent that title XXI of the Public Health Service Act ap-
19 plies to the action.

20 ~~(b) PREEMPTION.~~—The provisions of this subtitle
21 shall preempt any State law to the extent such law is in-
22 consistent with the limitations contained in such provi-
23 sions. The provisions of this subtitle shall not preempt any
24 State law that—

1 (1) provides for defenses in addition to those
 2 contained in this subtitle; places greater limitations
 3 on the amount of attorneys' fees that can be col-
 4 lected; or otherwise imposes greater restrictions on
 5 non-economic or punitive damages than those pro-
 6 vided in this subtitle;

7 (2) permits State officials to commence health
 8 care liability actions as a representative of an indi-
 9 vidual; or

10 (3) permits provider-based dispute resolution.

11 (c) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE
 12 OF LAW OR VENUE.—Nothing in this subtitle shall be con-
 13 strued to—

14 (1) waive or affect any defense of sovereign im-
 15 munity asserted by any State under any provision of
 16 law;

17 (2) waive or affect any defense of sovereign im-
 18 munity asserted by the United States;

19 (3) affect the applicability of any provision of
 20 the Foreign Sovereign Immunities Act of 1976;

21 (4) preempt State choice-of-law rules with re-
 22 spect to actions brought by a foreign nation or a cit-
 23 izen of a foreign nation; or

24 (5) affect the right of any court to transfer
 25 venue or to apply the law of a foreign nation or to

1 dismiss an action of a foreign nation or of a citizen
2 of a foreign nation on the ground of inconvenient
3 forum.

4 ~~(d) FEDERAL COURT JURISDICTION NOT ESTAB-~~
5 ~~LISHED ON FEDERAL QUESTION GROUNDS.—~~Nothing in
6 this subtitle shall be construed to establish any jurisdiction
7 in the district courts of the United States over health care
8 liability actions on the basis of sections 1331 or 1337 of
9 title 28, United States Code.

10 **SEC. 104. STATUTE OF LIMITATIONS.**

11 A health care liability action that is subject to this
12 Act may not be initiated unless a complaint with respect
13 to such action is filed within the 2-year period beginning
14 on the date on which the claimant discovered or, in the
15 exercise of reasonable care, should have discovered the
16 harm and its cause, except that such an action relating
17 to a claimant under legal disability may be filed within
18 2 years after the date on which the disability ceases. If
19 the commencement of a health care liability action is
20 stayed or enjoined, the running of the statute of limita-
21 tions under this section shall be suspended for the period
22 of the stay or injunction.

23 **SEC. 105. REFORM OF PUNITIVE DAMAGES.**

24 ~~(a) LIMITATION.—~~With respect to a health care li-
25 ability action, an award for punitive damages may only

1 be made, if otherwise permitted by applicable law, if it
 2 is proven by clear and convincing evidence that the defend-
 3 ant—

4 (1) intended to injure the claimant for a reason
 5 unrelated to the provision of health care services;

6 (2) understood the claimant was substantially
 7 certain to suffer unnecessary injury, and in provid-
 8 ing or failing to provide health care services, the de-
 9 fendant deliberately failed to avoid such injury; or

10 (3) acted with a conscious disregard of a sub-
 11 stantial and unjustifiable risk of unnecessary injury
 12 which the defendant failed to avoid in a manner
 13 which constitutes a gross deviation from the normal
 14 standard of conduct in such circumstances.

15 (b) PUNITIVE DAMAGES NOT PERMITTED.—Not-
 16 withstanding the provisions of subsection (a), punitive
 17 damages may not be awarded against a defendant with
 18 respect to any health care liability action if no judgment
 19 for compensatory damages, including nominal damages
 20 (under \$500), is rendered against the defendant.

21 (c) REQUIREMENTS FOR PLEADING OF PUNITIVE
 22 DAMAGES.—

23 (1) IN GENERAL.—No demand for punitive
 24 damages shall be included in a health care liability
 25 action as initially filed.

1 ~~(2) AMENDED PLEADING.~~—A court may allow a
 2 claimant to file an amended complaint or pleading
 3 for punitive damages in a health care liability action
 4 if—

5 ~~(A)~~ the claimant submits a motion to
 6 amend the complaint or pleading within the
 7 earlier of—

8 ~~(i)~~ 2 years after the complaint or ini-
 9 tial pleading is filed, or

10 ~~(ii)~~ 9 months before the date the mat-
 11 ter is first set for trial; and

12 ~~(B)~~ after a finding by a court upon review
 13 of supporting and opposing affidavits or after a
 14 hearing, that after weighing the evidence the
 15 claimant has established by a substantial prob-
 16 ability that the claimant will prevail on the
 17 claim for punitive damages.

18 ~~(d) SEPARATE PROCEEDING.~~—

19 ~~(1) IN GENERAL.~~—At the request of any de-
 20 fendant in a health care liability action, the trier of
 21 fact shall consider in a separate proceeding—

22 ~~(A)~~ whether punitive damages are to be
 23 awarded and the amount of such award, or

24 ~~(B)~~ the amount of punitive damages fol-
 25 lowing a determination of punitive liability.

1 ~~(2) ONLY RELEVANT EVIDENCE ADMISSIBLE.—~~

2 If a defendant requests a separate proceeding under
3 paragraph ~~(1)~~, evidence relevant only to the claim of
4 punitive damages in a health care liability action, as
5 determined by applicable State law, shall be inadmis-
6 sible in any proceeding to determine whether com-
7 pensatory damages are to be awarded.

8 ~~(c) DETERMINING AMOUNT OF PUNITIVE DAM-~~
9 ~~AGES.—~~In determining the amount of punitive damages
10 in a health care liability action, the trier of fact shall con-
11 sider only the following:

12 ~~(1) The severity of the harm caused by the con-~~
13 ~~duct of the defendant.~~

14 ~~(2) The duration of the conduct or any conceal-~~
15 ~~ment of it by the defendant.~~

16 ~~(3) The profitability of the conduct of the de-~~
17 ~~fendant.~~

18 ~~(4) The number of products sold or medical~~
19 ~~procedures rendered for compensation, as the case~~
20 ~~may be, by the defendant of the kind causing the~~
21 ~~harm complained of by the claimant.~~

22 ~~(5) Awards of punitive or exemplary damages~~
23 ~~to persons similarly situated to the claimant, when~~
24 ~~offered by the defendant.~~

1 (6) Prospective awards of compensatory dam-
2 ages to persons similarly situated to the claimant.

3 (7) Any criminal penalties imposed on the de-
4 fendant as a result of the conduct complained of by
5 the claimant, when offered by the defendant.

6 (8) The amount of any civil fines assessed
7 against the defendant as a result of the conduct
8 complained of by the claimant, when offered by the
9 defendant.

10 (f) LIMITATION AMOUNT.—The amount of damages
11 that may be awarded as punitive damages in any health
12 care liability action shall not exceed 3 times the amount
13 awarded to the claimant for the economic injury on which
14 such claim is based, or \$250,000, whichever is greater.
15 This subsection shall be applied by the court and shall
16 not be disclosed to the jury.

17 (g) RESTRICTIONS PERMITTED.—Nothing in this
18 section shall be construed to imply a right to seek punitive
19 damages where none exists under Federal or State law.

20 **SEC. 106. PERIODIC PAYMENTS.**

21 With respect to a health care liability action, no per-
22 son may be required to pay more than \$100,000 for future
23 damages in a single payment of a damages award, but
24 a person shall be permitted to make such payments of the
25 award on a periodic basis. The periods for such payments

1 shall be determined by the adjudicating body, based upon
2 projections of future losses and shall be reduced to present
3 value. The adjudicating body may waive the requirements
4 of this section if such body determines that such a waiver
5 is in the interests of justice.

6 **SEC. 107. SCOPE OF LIABILITY.**

7 (a) ~~IN GENERAL.~~—With respect to punitive and non-
8 economic damages, the liability of each defendant in a
9 health care liability action shall be several only and may
10 not be joint. Such a defendant shall be liable only for the
11 amount of punitive or noneconomic damages allocated to
12 the defendant in direct proportion to such defendant's per-
13 centage of fault or responsibility for the injury suffered
14 by the claimant.

15 (b) ~~DETERMINATION OF PERCENTAGE OF LIABIL-~~
16 ~~ITY.~~—The trier of fact in a health care liability action
17 shall determine the extent of each defendant's fault or re-
18 sponsibility for injury suffered by the claimant, and shall
19 assign a percentage of responsibility for such injury to
20 each such defendant.

21 (c) ~~PROHIBITION ON VICARIOUS LIABILITY.~~—A de-
22 fendant in a health care liability action may not be held
23 vicariously liable for the direct actions or omissions of
24 other individuals.

1 **SEC. 108. MANDATORY OFFSETS FOR DAMAGES PAID BY A**
 2 **COLLATERAL SOURCE.**

3 (a) ~~IN GENERAL.~~—With respect to a health care li-
 4 ability action, the total amount of damages received by
 5 an individual under such action shall be reduced, in ac-
 6 cordance with subsection (b), by any other payment that
 7 has been, or will be, made to an individual to compensate
 8 such individual for the injury that was the subject of such
 9 action.

10 (b) ~~AMOUNT OF REDUCTION.~~—The amount by which
 11 an award of damages to an individual for an injury shall
 12 be reduced under subsection (a) shall be—

13 (1) the total amount of any payments (other
 14 than such award) that have been made or that will
 15 be made to such individual to pay costs of or com-
 16 pensate such individual for the injury that was the
 17 subject of the action; minus

18 (2) the amount paid by such individual (or by
 19 the spouse, parent, or legal guardian of such individ-
 20 ual) to secure the payments described in paragraph
 21 (1).

22 (c) ~~PRETRIAL DETERMINATION OF AMOUNTS FROM~~
 23 ~~COLLATERAL SERVICES.~~—The reductions required under
 24 subsection (b)(2) shall be determined by the court in a
 25 pretrial proceeding. At such proceeding—

1 ~~(1)~~ no evidence shall be admitted as to the
 2 amount of any charge, payments, or damage for
 3 which a claimant—

4 ~~(A)~~ has received payment from a collateral
 5 source or the obligation for which has been as-
 6 sured by a third party; or

7 ~~(B)~~ is, or with reasonable certainty, will be
 8 eligible to receive payment from a collateral
 9 source of the obligation which will, with reason-
 10 able certainty be assumed by a third party; and
 11 ~~(2)~~ the jury, if any, shall be advised that—

12 ~~(A)~~ except for damages as to which the
 13 court permits the introduction of evidence, the
 14 claimant's medical expenses and lost income
 15 have been or will be paid by a collateral source
 16 or third party; and

17 ~~(B)~~ the claimant shall receive no award for
 18 any damages that have been or will be paid by
 19 a collateral source or third party.

20 **SEC. 109. TREATMENT OF ATTORNEYS' FEES AND OTHER**
 21 **COSTS.**

22 ~~(a)~~ LIMITATION ON AMOUNT OF CONTINGENCY
 23 FEES.—

24 ~~(1)~~ IN GENERAL.—An attorney who represents,
 25 on a contingency fee basis, a claimant in a health

1 care liability action may not charge, demand, re-
 2 ceive, or collect for services rendered in connection
 3 with such action in excess of the following amount
 4 recovered by judgment or settlement under such ac-
 5 tion:

6 (A) $33\frac{1}{3}$ percent of the first \$150,000 (or
 7 portion thereof) recovered, based on after-tax
 8 recovery, plus

9 (B) 25 percent of any amount in excess of
 10 \$150,000 recovered, based on after-tax recov-
 11 ery.

12 (2) CALCULATION OF PERIODIC PAYMENTS.—In
 13 the event that a judgment or settlement includes
 14 periodic or future payments of damages, the amount
 15 recovered for purposes of computing the limitation
 16 on the contingency fee under paragraph (1) shall be
 17 based on the cost of the annuity or trust established
 18 to make the payments. In any case in which an an-
 19 nuity or trust is not established to make such pay-
 20 ments, such amount shall be based on the present
 21 value of the payments.

22 (b) CONTINGENCY FEE DEFINED.—As used in this
 23 section, the term “contingency fee” means any fee for pro-
 24 fessional legal services which is, in whole or in part, con-

1 tingent upon the recovery of any amount of damages,
 2 whether through judgment or settlement.

3 **SEC. 110. OBSTETRIC CASES.**

4 With respect to a health care liability action relating
 5 to services provided during labor or the delivery of a baby,
 6 if the health care professional against whom the action
 7 is brought did not previously treat the pregnant woman
 8 for the pregnancy, the trier of fact may not find that the
 9 defendant committed malpractice and may not assess
 10 damages against the health care professional unless the
 11 malpractice is proven by clear and convincing evidence.

12 **SEC. 111. STATE-BASED ALTERNATIVE DISPUTE RESOLU-**
 13 **TION MECHANISMS.**

14 (a) APPLICATION TO HEALTH CARE LIABILITY
 15 CLAIMS UNDER HEALTH PLANS.—Prior to or immediately
 16 following the commencement of any health care liability
 17 action, the parties shall participate in the alternative dis-
 18 pute resolution system administered by the State under
 19 subsection (b). Such participation shall be in lieu of any
 20 other provision of Federal or State law applicable to the
 21 parties prior to the commencement of the health care li-
 22 ability action.

23 (b) ADOPTION OF MECHANISM BY STATE.—Each
 24 State shall—

1 ~~(1)~~ maintain or adopt at least one of the alter-
 2 native dispute resolution methods satisfying the re-
 3 quirements specified under subsection ~~(c)~~ and ~~(d)~~ for
 4 the resolution of health care liability claims arising
 5 from the provision of ~~(or failure to provide)~~ health
 6 care services to individuals enrolled in a health plan;
 7 and

8 ~~(2)~~ clearly disclose to enrollees in health plans
 9 ~~(and potential enrollees)~~ the availability and proce-
 10 dures for consumer grievances, including a descrip-
 11 tion of the alternative dispute resolution method or
 12 methods adopted under this subsection.

13 ~~(c)~~ SPECIFICATION OF PERMISSIBLE ALTERNATIVE
 14 DISPUTE RESOLUTION METHODS.—

15 ~~(1)~~ IN GENERAL.—The Attorney General, in
 16 consultation with the Secretary and the Administra-
 17 tive Conference of the United States, shall, by regu-
 18 lation, develop alternative dispute resolution methods
 19 for the use by States in resolving health care liability
 20 claims under subsection ~~(a)~~. Such methods shall in-
 21 clude at least the following:

22 ~~(A)~~ ARBITRATION.—The use of arbitra-
 23 tion, a nonjury adversarial dispute resolution
 24 process which may, subject to subsection ~~(d)~~,
 25 result in a final decision as to facts, law, liabil-

1 ity or damages. The parties may elect binding
2 arbitration.

3 (B) ~~MEDIATION.~~—The use of mediation, a
4 settlement process coordinated by a neutral
5 third party without the ultimate rendering of a
6 formal opinion as to factual or legal findings.

7 (C) ~~EARLY NEUTRAL EVALUATION.~~—The
8 use of early neutral evaluation, in which the
9 parties make a presentation to a neutral attor-
10 ney or other neutral evaluator for an assess-
11 ment of the merits, to encourage settlement. If
12 the parties do not settle as a result of assess-
13 ment and proceed to trial, the neutral eval-
14 uator's opinion shall be kept confidential.

15 (D) ~~EARLY OFFER AND RECOVERY MECHA-~~
16 NISM.—

17 (i) ~~IN GENERAL.~~—The use of early
18 offer and recovery mechanisms under
19 which a health care provider, health care
20 organization, or any other alleged respon-
21 sible defendant may offer to compensate a
22 claimant for his or her reasonable eco-
23 nomic damages, including future economic
24 damages, less amounts available from col-
25 lateral sources.

1 (ii) BINDING ARBITRATION.—If, after
2 an offer is made under clause (i), the
3 claimant alleges that payment of economic
4 damages under the offer has not been rea-
5 sonably made, or the participants in the
6 offer dispute their relative contributions to
7 the payments to be made to the claimant,
8 such disputes shall be resolved through
9 binding arbitration in accordance with ap-
10 plicable rules and procedures established
11 by the State involved.

12 ~~(2)~~ STANDARDS FOR ESTABLISHING METH-
13 ODS.—In developing alternative dispute resolution
14 methods under paragraph (1), the Attorney General
15 shall assure that the methods promote the resolution
16 of health care liability claims in a manner that—

17 (A) is affordable for the parties involved;

18 ~~(B)~~ provides for timely resolution of
19 claims;

20 (C) provides for the consistent and fair
21 resolution of claims; and

22 ~~(D)~~ provides for reasonably convenient ac-
23 cess to dispute resolution for individuals en-
24 rolled in plans.

1 (3) ~~WAIVER AUTHORITY.~~—Upon application of
2 a State, the Attorney General, in consultation with
3 the Secretary, may grant the State the authority to
4 fulfill the requirement of subsection (b) by adopting
5 a mechanism other than a mechanism established by
6 the Attorney General pursuant to this subsection,
7 except that such mechanism must meet the stand-
8 ards set forth in paragraph (2).

9 (d) ~~FURTHER REDRESS.~~—Except with respect to the
10 claimant-requested binding arbitration method set forth in
11 subsection (c)(1)(A), a claimant who is dissatisfied with
12 the determination reached as a result of an alternative dis-
13 pute resolution method applied under this section may,
14 after the final resolution of the claimant's claim under the
15 method, initiate or resume a cause of action to seek dam-
16 ages or other redress with respect to the claim to the ex-
17 tent otherwise permitted under State law. State law shall
18 govern the admissibility of results of any alternative dis-
19 pute resolution procedure and all statements, offers, and
20 other communications made during such procedures, at
21 any subsequent trial. An individual who initiates or re-
22 sumes a health care liability action shall only prevail if
23 such individual proves each element of the action beyond
24 a reasonable doubt, including proving that the defendant
25 was grossly negligent or intentionally caused injury.

1 **SEC. 112. REQUIREMENT OF CERTIFICATE OF MERIT.**

2 ~~(a) REQUIRING SUBMISSION WITH COMPLAINT.—Ex-~~
 3 ~~cept as provided in subsection (b) and subject to the pen-~~
 4 ~~alties of subsection (d), no health care liability action may~~
 5 ~~be brought by any individual unless, at the time the indi-~~
 6 ~~vidual commences such action, the individual or the indi-~~
 7 ~~vidual's attorney submits an affidavit declaring that—~~

8 ~~(1) the individual (or the individual's attorney)~~
 9 ~~has consulted and reviewed the facts of the claim~~
 10 ~~with a qualified specialist (as defined in subsection~~
 11 ~~(c));~~

12 ~~(2) the individual or the individual's attorney~~
 13 ~~has obtained a written report by a qualified special-~~
 14 ~~ist that clearly identifies the individual and that in-~~
 15 ~~cludes the specialist's determination that, based~~
 16 ~~upon a review of the available medical record and~~
 17 ~~other relevant material, a reasonable medical inter-~~
 18 ~~pretation of the facts supports a finding that the~~
 19 ~~claim against the defendant is meritorious and based~~
 20 ~~on good cause; and~~

21 ~~(3) on the basis of the qualified specialist's re-~~
 22 ~~view and consultation, the individual, and if rep-~~
 23 ~~resented, the individual's attorney, have concluded~~
 24 ~~that the claim is meritorious and based on good~~
 25 ~~cause.~~

26 ~~(b) EXTENSION IN CERTAIN INSTANCES.—~~

1 ~~(1) IN GENERAL.—Subject to paragraph (2),~~
2 ~~subsection (a) shall not apply with respect to an in-~~
3 ~~dividual who brings a health care liability action~~
4 ~~without submitting an affidavit described in such~~
5 ~~subsection if—~~

6 ~~(A) despite good faith efforts, the individ-~~
7 ~~ual is unable to obtain the written report before~~
8 ~~the expiration of the applicable statute of limi-~~
9 ~~tations;~~

10 ~~(B) despite good faith efforts, at the time~~
11 ~~the individual commences the action, the indi-~~
12 ~~vidual has been unable to obtain medical~~
13 ~~records or other information necessary, pursu-~~
14 ~~ant to any applicable law, to prepare the writ-~~
15 ~~ten report requested; or~~

16 ~~(C) the court of competent jurisdiction de-~~
17 ~~termines that the affidavit requirement shall be~~
18 ~~extended upon a showing of good cause.~~

19 ~~(2) DEADLINE FOR SUBMISSION WHERE EX-~~
20 ~~TENSION APPLIES.—In the case of an individual who~~
21 ~~brings an action to which paragraph (1) applies, the~~
22 ~~action shall be dismissed unless the individual sub-~~
23 ~~mits the affidavit described in subsection (a) not~~
24 ~~later than—~~

1 (A) in the case of an action to which sub-
 2 paragraph (A) of paragraph (1) applies, 90
 3 days after commencing the action; or

4 (B) in the case of an action to which sub-
 5 paragraph (B) of paragraph (1) applies, 90
 6 days after obtaining the information described
 7 in such subparagraph or when good cause for
 8 an extension no longer exists.

9 (c) QUALIFIED SPECIALIST DEFINED.—

10 (1) IN GENERAL.—As used in subsection (a),
 11 the term “qualified specialist” means, with respect
 12 to a health care liability action, a health care profes-
 13 sional who has expertise in the same or substantially
 14 similar area of practice to that involved in the
 15 action.

16 (2) EVIDENCE OF EXPERTISE.—For purposes
 17 of paragraph (1), evidence of required expertise may
 18 include evidence that the individual—

19 (A) practices (or has practiced) or teaches
 20 (or has taught) in the same or substantially
 21 similar area of health care or medicine to that
 22 involved in the action; or

23 (B) is otherwise qualified by experience or
 24 demonstrated competence in the relevant prac-
 25 tice area.

1 (d) ~~SANCTIONS FOR SUBMITTING FALSE AFFIDA-~~
2 ~~VIT.~~—Upon the motion of any party or on its own initia-
3 tive, the court in a health care liability action may impose
4 a sanction on a party, the party’s attorney, or both, for—
5 (1) any knowingly false statement made in an
6 affidavit described in subsection (a);
7 (2) making any false representations in order to
8 obtain a qualified specialist’s report; or
9 (3) failing to have the qualified specialist’s writ-
10 ten report in his or her custody and control;
11 and may require that the sanctioned party reimburse the
12 other party to the action for costs and reasonable attor-
13 ney’s fees.

14 **Subtitle B—Biomaterials Access** 15 **Assurance**

16 ~~SEC. 121. SHORT TITLE.~~

17 This subtitle may be cited as the “Biomaterials Ac-
18 cess Assurance Act of 1995”.

19 ~~SEC. 122. FINDINGS.~~

20 Congress finds that—

21 (1) each year millions of citizens of the United
22 States depend on the availability of lifesaving or life-
23 enhancing medical devices, many of which are per-
24 manently implantable within the human body;

1 (2) a continued supply of raw materials and
2 component parts is necessary for the invention, de-
3 velopment, improvement, and maintenance of the
4 supply of the devices;

5 (3) most of the medical devices are made with
6 raw materials and component parts that—

7 (A) are not designed or manufactured spe-
8 cifically for use in medical devices; and

9 (B) come in contact with internal human
10 tissue;

11 (4) the raw materials and component parts also
12 are used in a variety of nonmedical products;

13 (5) because small quantities of the raw mate-
14 rials and component parts are used for medical de-
15 vices, sales of raw materials and component parts
16 for medical devices constitute an extremely small
17 portion of the overall market for the raw materials
18 and medical devices;

19 (6) under the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 301 et seq.), manufacturers of
21 medical devices are required to demonstrate that the
22 medical devices are safe and effective, including
23 demonstrating that the products are properly de-
24 signed and have adequate warnings or instructions;

1 (7) notwithstanding the fact that raw materials
2 and component parts suppliers do not design,
3 produce, or test a final medical device, the suppliers
4 have been the subject of actions alleging inad-
5 equate—

6 (A) design and testing of medical devices
7 manufactured with materials or parts supplied
8 by the suppliers; or

9 (B) warnings related to the use of such
10 medical devices;

11 (8) even though suppliers of raw materials and
12 component parts have very rarely been held liable in
13 such actions, such suppliers have ceased supplying
14 certain raw materials and component parts for use
15 in medical devices because the costs associated with
16 litigation in order to ensure a favorable judgment for
17 the suppliers far exceeds the total potential sales
18 revenues from sales by such suppliers to the medical
19 device industry;

20 (9) unless alternate sources of supply can be
21 found, the unavailability of raw materials and com-
22 ponent parts for medical devices will lead to unavail-
23 ability of lifesaving and life-enhancing medical de-
24 vices;

1 (10) because other suppliers of the raw mate-
2 rials and component parts in foreign nations are re-
3 fusing to sell raw materials or component parts for
4 use in manufacturing certain medical devices in the
5 United States, the prospects for development of new
6 sources of supply for the full range of threatened
7 raw materials and component parts for medical de-
8 vices are remote;

9 (11) it is unlikely that the small market for
10 such raw materials and component parts in the
11 United States could support the large investment
12 needed to develop new suppliers of such raw mate-
13 rials and component parts;

14 (12) attempts to develop such new suppliers
15 would raise the cost of medical devices;

16 (13) courts that have considered the duties of
17 the suppliers of the raw materials and component
18 parts have generally found that the suppliers do not
19 have a duty—

20 (A) to evaluate the safety and efficacy of
21 the use of a raw material or component part in
22 a medical device; and

23 (B) to warn consumers concerning the
24 safety and effectiveness of a medical device;

1 ~~(14)~~ attempts to impose the duties referred to
 2 in subparagraphs (A) and (B) of paragraph (13) on
 3 suppliers of the raw materials and component parts
 4 would cause more harm than good by driving the
 5 suppliers to cease supplying manufacturers of medi-
 6 cal devices; and

7 ~~(15)~~ in order to safeguard the availability of a
 8 wide variety of lifesaving and life-enhancing medical
 9 devices, immediate action is needed—

10 (A) to clarify the permissible bases of li-
 11 ability for suppliers of raw materials and com-
 12 ponent parts for medical devices; and

13 (B) to provide expeditious procedures to
 14 dispose of unwarranted suits against the suppli-
 15 ers in such manner as to minimize litigation
 16 costs.

17 **SEC. 123. DEFINITIONS.**

18 As used in this subtitle:

19 (1) **BIOMATERIALS SUPPLIER.**—

20 (A) **IN GENERAL.**—The term “biomaterials
 21 supplier” means an entity that directly or indi-
 22 rectly supplies a component part or raw mate-
 23 rial for use in the manufacture of an implant.

24 (B) **PERSONS INCLUDED.**—Such term in-
 25 cludes any person who—

1 (i) has submitted master files to the
2 Secretary for purposes of premarket ap-
3 proval of a medical device; or

4 (ii) licenses a biomaterials supplier to
5 produce component parts or raw materials.

6 ~~(2) CLAIMANT.—~~

7 ~~(A) IN GENERAL.—~~The term “claimant”
8 means any person who brings a civil action, or
9 on whose behalf a civil action is brought, aris-
10 ing from harm allegedly caused directly or indi-
11 rectly by an implant, including a person other
12 than the individual into whose body, or in con-
13 tact with whose blood or tissue, the implant is
14 placed, who claims to have suffered harm as a
15 result of the implant.

16 ~~(B) ACTION BROUGHT ON BEHALF OF AN~~
17 ~~ESTATE.—~~With respect to an action brought on
18 behalf or through the estate of an individual
19 into whose body, or in contact with whose blood
20 or tissue the implant is placed, such term in-
21 cludes the decedent that is the subject of the
22 action.

23 ~~(C) ACTION BROUGHT ON BEHALF OF A~~
24 ~~MINOR.—~~With respect to an action brought on

1 behalf or through a minor, such term includes
2 the parent or guardian of the minor.

3 ~~(D) EXCLUSIONS.—Such term does not in-~~
4 clude—

5 (i) a provider of professional services,
6 in any case in which—

7 (I) the sale or use of an implant
8 is incidental to the transaction; and

9 (II) the essence of the trans-
10 action is the furnishing of judgment,
11 skill, or services; or

12 (ii) a manufacturer, seller, or
13 biomaterials supplier.

14 ~~(3) COMPONENT PART.—~~

15 ~~(A) IN GENERAL.—The term “component~~
16 ~~part” means a manufactured piece of an im-~~
17 ~~plant.~~

18 ~~(B) CERTAIN COMPONENTS.—Such term~~
19 includes a manufactured piece of an implant
20 that—

21 (i) has significant nonimplant applica-
22 tions; and

23 (ii) alone, has no implant value or
24 purpose, but when combined with other

1 component parts and materials, constitutes
2 an implant.

3 ~~(4) HARM.—~~

4 ~~(A) IN GENERAL.—~~The term “harm”
5 means—

6 ~~(i) any injury to or damage suffered~~
7 ~~by an individual;~~

8 ~~(ii) any illness, disease, or death of~~
9 ~~that individual resulting from that injury~~
10 ~~or damage; and~~

11 ~~(iii) any loss to that individual or any~~
12 ~~other individual resulting from that injury~~
13 ~~or damage.~~

14 ~~(B) EXCLUSION.—~~The term does not in-
15 clude any commercial loss or loss of or damage
16 to an implant.

17 ~~(5) IMPLANT.—~~The term “implant” means—

18 ~~(A) a medical device that is intended by~~
19 ~~the manufacturer of the device—~~

20 ~~(i) to be placed into a surgically or~~
21 ~~naturally formed or existing cavity of the~~
22 ~~body for a period of at least 30 days; or~~

23 ~~(ii) to remain in contact with bodily~~
24 ~~fluids or internal human tissue through a~~

1 surgically produced opening for a period of
2 less than 30 days; and

3 ~~(B) suture materials used in implant pro-~~
4 ~~cedures.~~

5 ~~(6) MANUFACTURER.—~~The term “manufac-
6 turer” means any person who, with respect to an im-
7 plant—

8 ~~(A) is engaged in the manufacture, prepa-~~
9 ~~ration, propagation, compounding, or processing~~
10 ~~(as defined in section 510(a)(1) of the Federal~~
11 ~~Food, Drug, and Cosmetic Act (21 U.S.C.~~
12 ~~360(a)(1)) of the implant; and~~

13 ~~(B) is required—~~

14 ~~(i) to register with the Secretary pur-~~
15 ~~suant to section 510 of the Federal Food,~~
16 ~~Drug, and Cosmetic Act (21 U.S.C. 360)~~
17 ~~and the regulations issued under such sec-~~
18 ~~tion; and~~

19 ~~(ii) to include the implant on a list of~~
20 ~~devices filed with the Secretary pursuant~~
21 ~~to section 510(j) of such Act (21 U.S.C.~~
22 ~~360(j)) and the regulations issued under~~
23 ~~such section.~~

24 ~~(7) MEDICAL DEVICE.—~~The term “medical de-
25 vice” means a device, as defined in section 201(h)

1 of the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 321(h)).

3 ~~(8) QUALIFIED SPECIALIST.~~—With respect to
4 an action, the term “qualified specialist” means a
5 person who is qualified by knowledge, skill, experi-
6 ence, training, or education in the specialty area
7 that is the subject of the action.

8 ~~(9) RAW MATERIAL.~~—The term “raw material”
9 means a substance or product that—

10 ~~(A)~~ has a generic use; and

11 ~~(B)~~ may be used in an application other
12 than an implant.

13 ~~(10) SECRETARY.~~—The term “Secretary”
14 means the Secretary of Health and Human Services.

15 ~~(11) SELLER.~~—

16 ~~(A) IN GENERAL.~~—The term “seller”
17 means a person who, in the course of a business
18 conducted for that purpose, sells, distributes,
19 leases, packages, labels, or otherwise places an
20 implant in the stream of commerce.

21 ~~(B) EXCLUSIONS.~~—The term does not in-
22 clude—

23 ~~(i)~~ a seller or lessor of real property;

24 ~~(ii)~~ a provider of professional services;

25 in any case in which the sale or use of an

1 implant is incidental to the transaction and
 2 the essence of the transaction is the fur-
 3 nishing of judgment, skill, or services; or
 4 (iii) any person who acts in only a fi-
 5 nancial capacity with respect to the sale of
 6 an implant.

7 **SEC. 124. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
 8 **EMPTION.**

9 ~~(a) GENERAL REQUIREMENTS.—~~

10 ~~(1) IN GENERAL.—~~In any civil action covered
 11 by this subtitle, a biomaterials supplier may raise
 12 any defense set forth in section 125.

13 ~~(2) PROCEDURES.—~~Notwithstanding any other
 14 provision of law, the Federal or State court in which
 15 a civil action covered by this subtitle is pending
 16 shall, in connection with a motion for dismissal or
 17 judgment based on a defense described in paragraph
 18 ~~(1)~~, use the procedures set forth in section 126.

19 ~~(b) APPLICABILITY.—~~

20 ~~(1) IN GENERAL.—~~Except as provided in para-
 21 graph ~~(2)~~, notwithstanding any other provision of
 22 law, this subtitle applies to any civil action brought
 23 by a claimant, whether in a Federal or State court,
 24 against a manufacturer, seller, or biomaterials sup-

1 plier, on the basis of any legal theory, for harm al-
 2 legedly caused by an implant.

3 ~~(2) EXCLUSION.~~—A civil action brought by a
 4 purchaser of a medical device for use in providing
 5 professional services against a manufacturer, seller,
 6 or biomaterials supplier for loss or damage to an im-
 7 plant or for commercial loss to the purchaser—

8 (A) shall not be considered an action that
 9 is subject to this subtitle; and

10 ~~(B)~~ shall be governed by applicable com-
 11 mercial or contract law.

12 ~~(c) SCOPE OF PREEMPTION.~~—

13 ~~(1) IN GENERAL.~~—This subtitle supersedes any
 14 State law regarding recovery for harm caused by an
 15 implant and any rule of procedure applicable to a
 16 civil action to recover damages for such harm only
 17 to the extent that this subtitle establishes a rule of
 18 law applicable to the recovery of such damages.

19 ~~(2) APPLICABILITY OF OTHER LAWS.~~—Any
 20 issue that arises under this subtitle and that is not
 21 governed by a rule of law applicable to the recovery
 22 of damages described in paragraph ~~(1)~~ shall be gov-
 23 erned by applicable Federal or State law.

24 ~~(d) STATUTORY CONSTRUCTION.~~—Nothing in this
 25 subtitle may be construed—

1 (1) to affect any defense available to a defend-
 2 ant under any other provisions of Federal or State
 3 law in an action alleging harm caused by an im-
 4 plant; or

5 (2) to create a cause of action or Federal court
 6 jurisdiction pursuant to section 1331 or 1337 of title
 7 28, United States Code, that otherwise would not
 8 exist under applicable Federal or State law.

9 **SEC. 125. LIABILITY OF BIOMATERIALS SUPPLIERS.**

10 (a) IN GENERAL.—

11 (1) EXCLUSION FROM LIABILITY.—Except as
 12 provided in paragraph (2), a biomaterials supplier
 13 shall not be liable for harm to a claimant caused by
 14 an implant.

15 (2) LIABILITY.—A biomaterials supplier that—

16 (A) is a manufacturer may be liable for
 17 harm to a claimant described in subsection (b);

18 (B) is a seller may be liable for harm to
 19 a claimant described in subsection (c); and

20 (C) furnishes raw materials or component
 21 parts that fail to meet applicable contractual re-
 22 quirements or specifications may be liable for a
 23 harm to a claimant described in subsection (d).

24 (b) LIABILITY AS MANUFACTURER.—

1 (1) IN GENERAL.—A biomaterials supplier may,
 2 to the extent required and permitted by any other
 3 applicable law, be liable for harm to a claimant
 4 caused by an implant if the biomaterials supplier is
 5 the manufacturer of the implant.

6 (2) GROUNDS FOR LIABILITY.—The
 7 biomaterials supplier may be considered the manu-
 8 facturer of the implant that allegedly caused harm
 9 to a claimant only if the biomaterials supplier—

10 (A)(i) has registered with the Secretary
 11 pursuant to section 510 of the Federal Food,
 12 Drug, and Cosmetic Act (21 U.S.C. 360) and
 13 the regulations issued under such section; and

14 (ii) included the implant on a list of de-
 15 vices filed with the Secretary pursuant to sec-
 16 tion 510(j) of such Act (21 U.S.C. 360(j)) and
 17 the regulations issued under such section; or

18 (B) is the subject of a declaration issued
 19 by the Secretary pursuant to paragraph (3)
 20 that states that the supplier, with respect to the
 21 implant that allegedly caused harm to the
 22 claimant, was required to—

23 (i) register with the Secretary under
 24 section 510 of such Act (21 U.S.C. 360);

1 and the regulations issued under such sec-
 2 tion, but failed to do so; or

3 (ii) include the implant on a list of de-
 4 vices filed with the Secretary pursuant to
 5 section 510(j) of such Act (21 U.S.C.
 6 360(j)) and the regulations issued under
 7 such section, but failed to do so.

8 (3) ADMINISTRATIVE PROCEDURES.—

9 (A) IN GENERAL.—The Secretary may
 10 issue a declaration described in paragraph
 11 (2)(B) on the motion of the Secretary or on pe-
 12 tition by any person, after providing—

13 (i) notice to the affected persons; and

14 (ii) an opportunity for an informal
 15 hearing.

16 (B) DOCKETING AND FINAL DECISION.—

17 Immediately upon receipt of a petition filed
 18 pursuant to this paragraph, the Secretary shall
 19 docket the petition. Not later than 180 days
 20 after the petition is filed, the Secretary shall
 21 issue a final decision on the petition.

22 (C) APPLICABILITY OF STATUTE OF LIMIT-

23 TATIONS.—Any applicable statute of limitations
 24 shall toll during the period during which a

1 claimant has filed a petition with the Secretary
2 under this paragraph.

3 ~~(c) LIABILITY AS SELLER.~~—A biomaterials supplier
4 may, to the extent required and permitted by any other
5 applicable law, be liable as a seller for harm to a claimant
6 caused by an implant if the biomaterials supplier—

7 (1) held title to the implant that allegedly
8 caused harm to the claimant as a result of purchas-
9 ing the implant after—

10 (A) the manufacture of the implant; and

11 (B) the entrance of the implant in the
12 stream of commerce; and

13 (2) subsequently resold the implant.

14 ~~(d) LIABILITY FOR VIOLATING CONTRACTUAL RE-~~
15 ~~QUIREMENTS OR SPECIFICATIONS.~~—A biomaterials sup-
16 plier may, to the extent required and permitted by any
17 other applicable law, be liable for harm to a claimant
18 caused by an implant, if the claimant in an action shows,
19 by a preponderance of the evidence, that—

20 (1) the raw materials or component parts deliv-
21 ered by the biomaterials supplier either—

22 (A) did not constitute the product de-
23 scribed in the contract between the biomaterials
24 supplier and the person who contracted for de-
25 livery of the product; or

1 ~~(B)~~ failed to meet any specifications that
2 were—

3 ~~(i)~~ provided to the biomaterials sup-
4 plier and not expressly repudiated by the
5 biomaterials supplier prior to acceptance of
6 delivery of the raw materials or component
7 parts;

8 ~~(ii)(I)~~ published by the biomaterials
9 supplier;

10 ~~(II)~~ provided to the manufacturer by
11 the biomaterials supplier; or

12 ~~(III)~~ contained in a master file that
13 was submitted by the biomaterials supplier
14 to the Secretary and that is currently
15 maintained by the biomaterials supplier for
16 purposes of premarket approval of medical
17 devices; or

18 ~~(iii)(I)~~ included in the submissions for
19 purposes of premarket approval or review
20 by the Secretary under section 510, 513,
21 515, or 520 of the Federal Food, Drug,
22 and Cosmetic Act (~~21 U.S.C. 360, 360c,~~
23 360e, or 360j); and

24 ~~(II)~~ have received clearance from the
25 Secretary,

1 if such specifications were provided by the man-
 2 ufacturer to the biomaterials supplier and were
 3 not expressly repudiated by the biomaterials
 4 supplier prior to the acceptance by the manu-
 5 facturer of delivery of the raw materials or
 6 component parts; and

7 (2) such conduct was an actual and proximate
 8 cause of the harm to the claimant.

9 **SEC. 126. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS**
 10 **AGAINST BIOMATERIALS SUPPLIERS.**

11 (a) MOTION TO DISMISS.—In any action that is sub-
 12 ject to this subtitle, a biomaterials supplier who is a de-
 13 fendant in such action may, at any time during which a
 14 motion to dismiss may be filed under an applicable law,
 15 move to dismiss the action on the grounds that—

16 (1) the defendant is a biomaterials supplier;
 17 and

18 (2)(A) the defendant should not, for the pur-
 19 poses of—

20 (i) section 125(b), be considered to be a
 21 manufacturer of the implant that is subject to
 22 such section; or

23 (ii) section 125(c), be considered to be a
 24 seller of the implant that allegedly caused harm
 25 to the claimant; or

1 ~~(B)(i)~~ the claimant has failed to establish, pur-
 2 suant to section 125(d), that the supplier furnished
 3 raw materials or component parts in violation of
 4 contractual requirements or specifications; or

5 (ii) the claimant has failed to comply with the
 6 procedural requirements of subsection (b).

7 ~~(b) PROCEDURAL REQUIREMENTS.—~~

8 (1) IN GENERAL.—The procedural requirements
 9 described in paragraphs (2) and (3) shall apply to
 10 any action by a claimant against a biomaterials sup-
 11 plier that is subject to this subtitle.

12 ~~(2) MANUFACTURER OF IMPLANT SHALL BE~~
 13 ~~NAMED A PARTY.—~~The claimant shall be required to
 14 name the manufacturer of the implant as a party to
 15 the action, unless—

16 (A) the manufacturer is subject to service
 17 of process solely in a jurisdiction in which the
 18 biomaterials supplier is not domiciled or subject
 19 to a service of process; or

20 (B) an action against the manufacturer is
 21 barred by applicable law.

22 (3) AFFIDAVIT.—At the time the claimant
 23 brings an action against a biomaterials supplier the
 24 claimant shall be required to submit an affidavit
 25 that—

1 (A) declares that the claimant has con-
2 sulted and reviewed the facts of the action with
3 a qualified specialist, whose qualifications the
4 claimant shall disclose;

5 (B) includes a written determination by a
6 qualified specialist that the raw materials or
7 component parts actually used in the manufac-
8 ture of the implant of the claimant were raw
9 materials or component parts described in sec-
10 tion 125(d)(1), together with a statement of the
11 basis for such a determination;

12 (C) includes a written determination by a
13 qualified specialist that, after a review of the
14 medical record and other relevant material, the
15 raw material or component part supplied by the
16 biomaterials supplier and actually used in the
17 manufacture of the implant was a cause of the
18 harm alleged by claimant, together with a state-
19 ment of the basis for the determination; and

20 (D) states that, on the basis of review and
21 consultation of the qualified specialist, the
22 claimant (or the attorney of the claimant) has
23 concluded that there is a reasonable and meri-
24 torious cause for the filing of the action against
25 the biomaterials supplier.

1 ~~(c) PROCEEDING ON MOTION TO DISMISS.~~—The fol-
 2 lowing rules shall apply to any proceeding on a motion
 3 to dismiss filed under this section:

4 ~~(1) AFFIDAVITS RELATING TO LISTING AND~~
 5 ~~DECLARATIONS.~~—

6 ~~(A) IN GENERAL.~~—The defendant in the
 7 action may submit an affidavit demonstrating
 8 that defendant has not included the implant on
 9 a list, if any, filed with the Secretary pursuant
 10 to section 510(j) of the Federal Food, Drug,
 11 and Cosmetic Act (21 U.S.C. 360(j)).

12 ~~(B) RESPONSE TO MOTION TO DISMISS.~~—
 13 In response to the motion to dismiss, the claim-
 14 ant may submit an affidavit demonstrating
 15 that—

16 (i) the Secretary has, with respect to
 17 the defendant and the implant that alleg-
 18 edly caused harm to the claimant, issued a
 19 declaration pursuant to section
 20 125(b)(2)(B); or

21 (ii) the defendant who filed the mo-
 22 tion to dismiss is a seller of the implant
 23 who is liable under section 125(c).

24 ~~(2) EFFECT OF MOTION TO DISMISS ON DIS-~~
 25 ~~COVERY.~~—

1 (A) IN GENERAL.—If a defendant files a
 2 motion to dismiss under paragraph (1) or (3) of
 3 subsection (a), no discovery shall be permitted
 4 in connection to the action that is the subject
 5 of the motion, other than discovery necessary
 6 to determine a motion to dismiss for lack of ju-
 7 risdiction, until such time as the court rules on
 8 the motion to dismiss in accordance with the
 9 affidavits submitted by the parties in accord-
 10 ance with this section.

11 (B) DISCOVERY.—If a defendant files a
 12 motion to dismiss under subsection (a)(2) on
 13 the grounds that the biomaterials supplier did
 14 not furnish raw materials or component parts
 15 in violation of contractual requirements or spec-
 16 ifications, the court may permit discovery, as
 17 ordered by the court. The discovery conducted
 18 pursuant to this subparagraph shall be limited
 19 to issues that are directly relevant to—

- 20 (i) the pending motion to dismiss; or
- 21 (ii) the jurisdiction of the court.

22 (3) AFFIDAVITS RELATING STATUS OF DEFEND-
 23 ANT.—

24 (A) IN GENERAL.—Except as provided in
 25 clauses (i) and (ii) of subparagraph (B), the

1 court shall consider a defendant to be a
2 biomaterials supplier who is not subject to an
3 action for harm to a claimant caused by an im-
4 plant, other than an action relating to liability
5 for a violation of contractual requirements or
6 specifications described in subsection (d).

7 (B) RESPONSES TO MOTION TO DISMISS.—

8 The court shall grant a motion to dismiss any
9 action that asserts liability of the defendant
10 under subsection (b) or (c) of section 125 on
11 the grounds that the defendant is not a manu-
12 facturer subject to such subsection 125(b) or
13 seller subject to subsection 125(c), unless the
14 claimant submits a valid affidavit that dem-
15 onstrates that—

16 (i) with respect to a motion to dismiss
17 contending the defendant is not a manu-
18 facturer, the defendant meets the applica-
19 ble requirements for liability as a manufac-
20 turer under section 125(b); or

21 (ii) with respect to a motion to dis-
22 miss contending that the defendant is not
23 a seller, the defendant meets the applicable
24 requirements for liability as a seller under
25 section 125(c).

1 ~~(4) BASIS OF RULING ON MOTION TO DIS-~~
 2 ~~MISS.—~~

3 ~~(A) IN GENERAL.—~~The court shall rule on
 4 a motion to dismiss filed under subsection (a)
 5 solely on the basis of the pleadings of the par-
 6 ties made pursuant to this section and any affi-
 7 davits submitted by the parties pursuant to this
 8 section.

9 ~~(B) MOTION FOR SUMMARY JUDGMENT.—~~
 10 Notwithstanding any other provision of law, if
 11 the court determines that the pleadings and af-
 12 fidavits made by parties pursuant to this sec-
 13 tion raise genuine issues as concerning material
 14 facts with respect to a motion concerning con-
 15 tractual requirements and specifications, the
 16 court may deem the motion to dismiss to be a
 17 motion for summary judgment made pursuant
 18 to subsection (d).

19 ~~(d) SUMMARY JUDGMENT.—~~

20 ~~(1) IN GENERAL.—~~

21 ~~(A) BASIS FOR ENTRY OF JUDGMENT.—~~A
 22 biomaterials supplier shall be entitled to entry
 23 of judgment without trial if the court finds
 24 there is no genuine issue as concerning any ma-

1 terial fact for each applicable element set forth
2 in paragraphs (1) and (2) of section 125(d).

3 ~~(B) ISSUES OF MATERIAL FACT.—~~With re-
4 spect to a finding made under subparagraph
5 (A), the court shall consider a genuine issue of
6 material fact to exist only if the evidence sub-
7 mitted by claimant would be sufficient to allow
8 a reasonable jury to reach a verdict for the
9 claimant if the jury found the evidence to be
10 credible.

11 ~~(2) DISCOVERY MADE PRIOR TO A RULING ON~~
12 ~~A MOTION FOR SUMMARY JUDGMENT.—~~If, under ap-
13 plicable rules, the court permits discovery prior to a
14 ruling on a motion for summary judgment made
15 pursuant to this subsection, such discovery shall be
16 limited solely to establishing whether a genuine issue
17 of material fact exists.

18 ~~(3) DISCOVERY WITH RESPECT TO A~~
19 ~~BIOMATERIALS SUPPLIER.—~~A biomaterials supplier
20 shall be subject to discovery in connection with a
21 motion seeking dismissal or summary judgment on
22 the basis of the inapplicability of section 125(d) or
23 the failure to establish the applicable elements of
24 section 125(d) solely to the extent permitted by the

1 applicable Federal or State rules for discovery
2 against nonparties.

3 ~~(e) STAY PENDING PETITION FOR DECLARATION.—~~

4 If a claimant has filed a petition for a declaration pursu-
5 ant to section 125(b) with respect to a defendant, and the
6 Secretary has not issued a final decision on the petition,
7 the court shall stay all proceedings with respect to that
8 defendant until such time as the Secretary has issued a
9 final decision on the petition.

10 ~~(f) MANUFACTURER CONDUCT OF PROCEEDING.—~~

11 The manufacturer of an implant that is the subject of an
12 action covered under this subtitle shall be permitted to file
13 and conduct a proceeding on any motion for summary
14 judgment or dismissal filed by a biomaterials supplier who
15 is a defendant under this section if the manufacturer and
16 any other defendant in such action enter into a valid and
17 applicable contractual agreement under which the manu-
18 facturer agrees to bear the cost of such proceeding or to
19 conduct such proceeding.

20 ~~(g) ATTORNEY FEES.—~~The court shall require the
21 claimant to compensate the biomaterials supplier (or a
22 manufacturer appearing in lieu of a supplier pursuant to
23 subsection (f)) for attorney fees and costs, if—

24 ~~(1)~~ the claimant named or joined the
25 biomaterials supplier; and

1 (2) the court found the claim against the
2 biomaterials supplier to be without merit and frivo-
3 lous.

4 **Subtitle C—Applicability**

5 ~~SEC. 131. APPLICABILITY.~~

6 This title shall apply to all civil actions covered under
7 this title that are commenced on or after the date of enact-
8 ment of this Act, including any such action with respect
9 to which the harm asserted in the action or the conduct
10 that caused the harm occurred before the date of enact-
11 ment of this Act.

12 **TITLE II—PROTECTION OF THE** 13 **HEALTH AND SAFETY OF PA-** 14 **TIENTS**

15 ~~SEC. 201. HEALTH CARE QUALITY ASSURANCE PROGRAM.~~

16 (a) ~~FUND.~~—Each State shall establish a health care
17 quality assurance program, to be approved by the Sec-
18 retary, and a fund consisting of such amounts as are
19 transferred to the fund under subsection (b).

20 (b) ~~TRANSFER OF AMOUNTS.~~—Each State shall re-
21 quire that 50 percent of all awards of punitive damages
22 resulting from all health care liability actions in that State
23 be transferred to the fund established under subsection
24 (a) in the State.

1 ~~(c) OBLIGATIONS FROM FUND.~~—The chief executive
 2 officer of a State shall obligate such sums as are available
 3 in the fund established in that State under subsection (a)
 4 to—

5 (1) license and certify health care professionals
 6 in the State;

7 (2) implement health care quality assurance
 8 programs; and

9 (3) carry out programs to reduce malpractice-
 10 related costs for health care providers volunteering
 11 to provide health care services in medically under-
 12 served areas.

13 **~~SEC. 202. RISK MANAGEMENT PROGRAMS.~~**

14 ~~(a) REQUIREMENTS FOR PROVIDERS.~~—Each State
 15 shall require each health care professional and health care
 16 provider providing services in the State to participate in
 17 a risk management program to prevent and provide early
 18 warning of practices which may result in injuries to pa-
 19 tients or which otherwise may endanger patient safety.

20 ~~(b) REQUIREMENTS FOR INSURERS.~~—Each State
 21 shall require each entity which provides health care profes-
 22 sional or provider liability insurance to health care profes-
 23 sionals and health care providers in the State to—

24 (1) establish risk management programs based
 25 on data available to such entity or sanction pro-

1 grams of risk management for health care profes-
 2 sionals and health care providers provided by other
 3 entities; and

4 (2) require each such professional or provider,
 5 as a condition of maintaining insurance, to partici-
 6 pate in one program described in paragraph (1) at
 7 least once in each 3-year period.

8 **SEC. 203. NATIONAL PRACTITIONER DATA BANK.**

9 Section 427 of the Health Care Quality Improvement
 10 Act of 1986 (42 U.S.C. 11137) is amended—

11 (1) by redesignating subsections (b) through (d)
 12 as subsections (c) through (e), respectively;

13 (2) by inserting after subsection (a), the follow-
 14 ing new subsection:

15 “(b) DISCLOSURE OF INFORMATION.—The Secretary
 16 shall promulgate regulations providing for the disclosure
 17 of information reported to the Secretary under sections
 18 422 and 423, upon request, to any individual.”; and

19 (3) in subsection (c) (as so redesignated)—

20 (A) in the first sentence of paragraph (1),
 21 by striking “under this part” and inserting
 22 “under section 421”; and

23 (B) in paragraph (3), by striking “sub-
 24 section (a)” and inserting “subsections (a) and
 25 (b)”.

1 **TITLE III—SEVERABILITY**

2 **SEC. 301. SEVERABILITY.**

3 If any provision of this Act, an amendment made by
 4 this Act, or the application of such provision or amend-
 5 ment to any person or circumstance is held to be unconsti-
 6 tutional, the remainder of this Act, the amendments made
 7 by this Act, and the application of the provisions of such
 8 to any person or circumstance shall not be affected
 9 thereby.

10 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

11 (a) *SHORT TITLE.*—This Act may be cited as the
 12 “Health Care Liability Reform and Quality Assurance Act
 13 of 1995”.

14 (b) *TABLE OF CONTENTS.*—The table of contents is as
 15 follows:

Sec. 1. Short title; table of contents.

TITLE I—HEALTH CARE LIABILITY REFORM

Subtitle A—Liability Reform

Sec. 101. Findings and purpose.

Sec. 102. Definitions.

Sec. 103. Applicability.

Sec. 104. Statute of limitations.

Sec. 105. Reform of punitive damages.

Sec. 106. Periodic payments.

Sec. 107. Scope of liability.

Sec. 108. Mandatory offsets for damages paid by a collateral source.

Sec. 109. Treatment of attorneys’ fees and other costs.

Sec. 110. State-based alternative dispute resolution mechanisms.

Subtitle B—Biomaterials Access Assurance

Sec. 121. Short title.

Sec. 122. Findings.

Sec. 123. Definitions.

Sec. 124. General requirements; applicability; preemption.

Sec. 125. Liability of biomaterials suppliers.

Sec. 126. Procedures for dismissal of civil actions against biomaterials suppliers.

Subtitle C—Applicability

Sec. 131. Applicability.

TITLE II—PROTECTION OF THE HEALTH AND SAFETY OF PATIENTS

Sec. 201. Additional resources for State health care quality assurance and access activities.

Sec. 202. Quality assurance, patient safety, and consumer information.

TITLE III—SEVERABILITY

Sec. 301. Severability.

1 ***TITLE I—HEALTH CARE***
 2 ***LIABILITY REFORM***
 3 ***Subtitle A—Liability Reform***

4 ***SEC. 101. FINDINGS AND PURPOSE.***

5 (a) *FINDINGS.—Congress finds the following:*

6 (1) *EFFECT ON HEALTH CARE ACCESS AND*
 7 *COSTS.—The civil justice system of the United States*
 8 *is a costly and inefficient mechanism for resolving*
 9 *claims of health care liability and compensating in-*
 10 *jured patients and the problems associated with the*
 11 *current system are having an adverse impact on the*
 12 *availability of, and access to, health care services and*
 13 *the cost of health care in the United States.*

14 (2) *EFFECT ON INTERSTATE COMMERCE.—The*
 15 *health care and insurance industries are industries*
 16 *affecting interstate commerce and the health care li-*
 17 *ability litigation systems existing throughout the*
 18 *United States affect interstate commerce by contribut-*

1 *ing to the high cost of health care and premiums for*
 2 *health care liability insurance purchased by partici-*
 3 *pants in the health care system.*

4 (3) *EFFECT ON FEDERAL SPENDING.*—*The health*
 5 *care liability litigation systems existing throughout*
 6 *the United States have a significant effect on the*
 7 *amount, distribution, and use of Federal funds be-*
 8 *cause of—*

9 (A) *the large number of individuals who re-*
 10 *ceive health care benefits under programs oper-*
 11 *ated or financed by the Federal Government;*

12 (B) *the large number of individuals who*
 13 *benefit because of the exclusion from Federal*
 14 *taxes of the amounts spent to provide such indi-*
 15 *viduals with health insurance benefits; and*

16 (C) *the large number of health care provid-*
 17 *ers who provide items or services for which the*
 18 *Federal Government makes payments.*

19 (b) *PURPOSE.*—*It is the purpose of this Act to imple-*
 20 *ment reasonable, comprehensive, and effective health care*
 21 *liability reform that is designed to—*

22 (1) *ensure that individuals with meritorious*
 23 *health care injury claims receive fair and adequate*
 24 *compensation;*

1 (2) *improve the availability of health care service*
2 *in cases in which health care liability actions have*
3 *been shown to be a factor in the decreased availability*
4 *of services; and*

5 (3) *improve the fairness and cost-effectiveness of*
6 *the current health care liability system of the United*
7 *States to resolve disputes over, and provide compensa-*
8 *tion for, health care liability by reducing uncertainty*
9 *and unpredictability in the amount of compensation*
10 *provided to injured individuals.*

11 **SEC. 102. DEFINITIONS.**

12 *As used in this subtitle:*

13 (1) *CLAIMANT.*—The term “claimant” means
14 *any person who commences a health care liability ac-*
15 *tion, and any person on whose behalf such an action*
16 *is commenced, including the decedent in the case of*
17 *an action brought through or on behalf of an estate.*

18 (2) *CLEAR AND CONVINCING EVIDENCE.*—The
19 term “clear and convincing evidence” means that
20 *measure or degree of proof that will produce in the*
21 *mind of the trier of fact a firm belief or conviction*
22 *as to the truth of the allegations sought to be estab-*
23 *lished, except that such measure or degree of proof is*
24 *more than that required under preponderance of the*

1 evidence, but less than that required for proof beyond
2 a reasonable doubt.

3 (3) *COLLATERAL SOURCE RULE.*—The term “col-
4 lateral source rule” means a rule, either statutorily
5 established or established at common law, that pre-
6 vents the introduction of evidence regarding collateral
7 source benefits or that prohibits the deduction of col-
8 lateral source benefits from an award of damages in
9 a health care liability action.

10 (4) *ECONOMIC LOSSES.*—The term “economic
11 losses” means objectively verifiable monetary losses in-
12 curred as a result of the provision of (or failure to
13 provide or pay for) health care services or the use of
14 a medical product, including past and future medical
15 expenses, loss of past and future earnings, cost of ob-
16 taining replacement services in the home (including
17 child care, transportation, food preparation, and
18 household care), cost of making reasonable accom-
19 modations to a personal residence, loss of employ-
20 ment, and loss of business or employment opportuni-
21 ties. Economic losses are neither noneconomic losses
22 nor punitive damages.

23 (5) *HEALTH CARE LIABILITY ACTION.*—The term
24 “health care liability action” means a civil action
25 against a health care provider, health care profes-

1 sional, health plan, or other defendant, including a
 2 right to legal or equitable contribution, indemnity,
 3 subrogation, third-party claims, cross claims, or
 4 counter-claims, in which the claimant alleges injury
 5 related to the provision of, payment for, or the failure
 6 to provide or pay for, health care services or medical
 7 products, regardless of the theory of liability on which
 8 the action is based. Such term does not include a
 9 product liability action, except where such an action
 10 is brought as part of a broader health care liability
 11 action.

12 (6) *HEALTH PLAN.*—The term “health plan”
 13 means any person or entity which is obligated to pro-
 14 vide or pay for health benefits under any health in-
 15 surance arrangement, including any person or entity
 16 acting under a contract or arrangement to provide,
 17 arrange for, or administer any health benefit.

18 (7) *HEALTH CARE PROFESSIONAL.*—The term
 19 “health care professional” means any individual who
 20 provides health care services in a State and who is
 21 required by Federal or State laws or regulations to be
 22 licensed, registered or certified to provide such services
 23 or who is certified to provide health care services pur-
 24 suant to a program of education, training and exam-

1 *ination by an accredited institution, professional*
2 *board, or professional organization.*

3 (8) *HEALTH CARE PROVIDER.*—The term “health
4 *care provider” means any organization or institution*
5 *that is engaged in the delivery of health care items or*
6 *services in a State and that is required by Federal or*
7 *State laws or regulations to be licensed, registered or*
8 *certified to engage in the delivery of such items or*
9 *services.*

10 (9) *HEALTH CARE SERVICES.*—The term “health
11 *care services” means any services provided by a*
12 *health care professional, health care provider, or*
13 *health plan or any individual working under the su-*
14 *pervision of a health care professional, that relate to*
15 *the diagnosis, prevention, or treatment of any disease*
16 *or impairment, or the assessment of the health of*
17 *human beings.*

18 (10) *INJURY.*—The term “injury” means any ill-
19 *ness, disease, or other harm that is the subject of a*
20 *health care liability action.*

21 (11) *MEDICAL PRODUCT.*—The term “medical
22 *product” means a drug (as defined in section*
23 *201(g)(1) of the Federal Food, Drug, and Cosmetic*
24 *Act (21 U.S.C. 321(g)(1)) or a medical device as de-*
25 *fin ed in section 201(h) of such Act (21 U.S.C.*

1 321(h)), including any component or raw material
 2 used therein, but excluding health care services, as de-
 3 fined in paragraph (9).

4 (12) *NONECONOMIC LOSSES*.—The term “non-
 5 economic losses” means losses for physical and emo-
 6 tional pain, suffering, inconvenience, physical im-
 7 pairment, mental anguish, disfigurement, loss of en-
 8 joyment of life, loss of consortium, loss of society or
 9 companionship (other than loss of domestic services),
 10 and other nonpecuniary losses incurred by an indi-
 11 vidual with respect to which a health care liability
 12 action is brought. Noneconomic losses are neither eco-
 13 nomic losses nor punitive damages.

14 (13) *PUNITIVE DAMAGES*.—The term “punitive
 15 damages” means damages awarded, for the purpose of
 16 punishment or deterrence, and not for compensatory
 17 purposes, against a health care professional, health
 18 care provider, or other defendant in a health care li-
 19 ability action. Punitive damages are neither economic
 20 nor noneconomic damages.

21 (14) *SECRETARY*.—The term “Secretary” means
 22 the Secretary of Health and Human Services.

23 (15) *STATE*.—The term “State” means each of
 24 the several States of the United States, the District of
 25 Columbia, and the Commonwealth of Puerto Rico.

1 **SEC. 103. APPLICABILITY.**

2 (a) *IN GENERAL.*—Except as provided in subsections
3 (c) and (d), this subtitle shall apply with respect to any
4 health care liability action brought in any Federal or State
5 court, except that this subtitle shall not apply to an action
6 for damages arising from a vaccine-related injury or death
7 to the extent that title XXI of the Public Health Service
8 Act applies to the action.

9 (b) *PREEMPTION.*—

10 (1) *IN GENERAL.*—The provisions of this subtitle
11 shall preempt any State law existing on, or enacted
12 subsequent to, the date of enactment of this Act, only
13 to the extent that such law is inconsistent with the
14 limitations contained in such provisions and shall
15 not preempt State law to the extent that such law—

16 (A) places greater restrictions on the
17 amount of or standards for awarding non-
18 economic or punitive damages;

19 (B) places greater limitations on the award-
20 ing of attorneys fees for awards in excess of
21 \$150,000;

22 (C) permits a lower threshold for the peri-
23 odic payment of future damages;

24 (D) establishes a shorter period during
25 which a health care liability action may be initi-
26 ated or a more restrictive rule with respect to the

1 *time at which the period of limitations begins to*
 2 *run; or*

3 *(E) implements collateral source rule reform*
 4 *that either permits the introduction of evidence*
 5 *of collateral source benefits or provides for the*
 6 *mandatory offset of collateral source benefits*
 7 *from damage awards.*

8 *(2) RULES OF CONSTRUCTION.—The provisions*
 9 *of this subtitle shall not be construed to preempt any*
 10 *State law that—*

11 *(A) permits State officials to commence*
 12 *health care liability actions as a representative*
 13 *of an individual;*

14 *(B) permits provider-based dispute resolu-*
 15 *tion;*

16 *(C) places a maximum limit on the total*
 17 *damages in a health care liability action;*

18 *(D) places a maximum limit on the time in*
 19 *which a health care liability action may be initi-*
 20 *ated; or*

21 *(E) provides for defenses in addition to*
 22 *those contained in this Act.*

23 *(c) STATE OPTION.—*

24 *(1) IN GENERAL.—With respect to a provision of*
 25 *this subtitle, such provision shall not apply to a*

1 *health care liability action involving parties that are*
 2 *residents of the same State if the action is brought*
 3 *in a court of that State and the State has enacted*
 4 *a law—*

5 *(A) specifically citing the authority of this*
 6 *subsection; and*

7 *(B)(i) proclaiming that the State has deter-*
 8 *mined that such provision shall not apply to*
 9 *such actions; or*

10 *(ii) establishing provisions that specifically*
 11 *contradict the provisions of this subtitle.*

12 *(2) MULTIPLE STATES.—With respect to a health*
 13 *care liability action involving parties that are resi-*
 14 *dents of more than one State, if each such State has*
 15 *enacted a law described in paragraph (1), the choice-*
 16 *of-law rules of each such State shall govern the rules*
 17 *and procedures applicable in the action.*

18 *(3) CORPORATE ENTITY.—For purposes of this*
 19 *subsection, a corporate entity shall be deemed to be a*
 20 *resident of the State in which such entity is incor-*
 21 *porated and the State in which the principal place of*
 22 *business of the entity is located.*

23 *(4) RULE OF CONSTRUCTION.—Nothing in this*
 24 *subsection shall be construed as requiring a State to*
 25 *reenact any provision of State law if such law existed*

1 *on the date of enactment of this Act and such law is*
 2 *not otherwise preempted under the provisions of sub-*
 3 *section (b).*

4 *(d) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE OF*
 5 *LAW OR VENUE.—Nothing in this subtitle shall be construed*
 6 *to—*

7 *(1) waive or affect any defense of sovereign im-*
 8 *munity asserted by any State under any provision of*
 9 *law;*

10 *(2) waive or affect any defense of sovereign im-*
 11 *munity asserted by the United States;*

12 *(3) affect the applicability of any provision of*
 13 *the Foreign Sovereign Immunities Act of 1976;*

14 *(4) preempt State choice-of-law rules with re-*
 15 *spect to actions brought by a foreign nation or a citi-*
 16 *zen of a foreign nation;*

17 *(5) affect the right of any court to transfer venue*
 18 *or to apply the law of a foreign nation or to dismiss*
 19 *an action of a foreign nation or of a citizen of a for-*
 20 *ign nation on the ground of inconvenient forum; or*

21 *(6) supersede any provision of Federal law.*

22 *(e) FEDERAL COURT JURISDICTION NOT ESTAB-*
 23 *LISHED ON FEDERAL QUESTION GROUNDS.—Nothing in*
 24 *this subtitle shall be construed to establish any jurisdiction*
 25 *in the district courts of the United States over health care*

1 *liability actions on the basis of section 1331 or 1337 of title*
 2 *28, United States Code.*

3 **SEC. 104. STATUTE OF LIMITATIONS.**

4 *A health care liability action that is subject to this*
 5 *Act may not be initiated unless a complaint with respect*
 6 *to such action is filed within the 2-year period beginning*
 7 *on the date on which the claimant discovered or, in the exer-*
 8 *cise of reasonable care, should have discovered the injury*
 9 *and its cause, except that such an action relating to a*
 10 *claimant under legal disability may be filed within 2 years*
 11 *after the date on which the disability ceases. If the com-*
 12 *mencement of a health care liability action is stayed or en-*
 13 *joined, the running of the statute of limitations under this*
 14 *section shall be suspended for the period of the stay or in-*
 15 *junction.*

16 **SEC. 105. REFORM OF PUNITIVE DAMAGES.**

17 *(a) LIMITATION.—With respect to a health care liabil-*
 18 *ity action, an award for punitive damages may only be*
 19 *made, if otherwise permitted by applicable law, if it is*
 20 *proven by clear and convincing evidence that the defend-*
 21 *ant—*

22 *(1) intended to injure the claimant for a reason*
 23 *unrelated to the provision of health care services;*

24 *(2) understood the claimant was substantially*
 25 *certain to suffer unnecessary injury, and in providing*

1 or failing to provide health care services, the defend-
2 ant deliberately failed to avoid such injury; or

3 (3) acted with a conscious, flagrant disregard of
4 a substantial and unjustifiable risk of unnecessary in-
5 jury which the defendant failed to avoid in a manner
6 which constitutes a gross deviation from the normal
7 standard of conduct in such circumstances.

8 (b) *PUNITIVE DAMAGES NOT PERMITTED.*—Notwith-
9 standing the provisions of subsection (a), punitive damages
10 may not be awarded against a defendant with respect to
11 any health care liability action if no judgment for compen-
12 satory damages, including nominal damages (under \$500),
13 is rendered against the defendant.

14 (c) *PROCEDURE FOR DETERMINING PUNITIVE DAM-*
15 *AGES.*—

16 (1) *IN GENERAL.*—In any health care liability
17 action subject to this subtitle in which punitive dam-
18 ages are recoverable, the trier of fact shall determine,
19 concurrent with all other issues presented in such ac-
20 tion, whether such damages shall be allowed. If the
21 trier of fact determines that such damages are al-
22 lowed, a separate proceeding shall be conducted by the
23 court to determine the amount of such damages to be
24 awarded.

1 (2) *SEPARATE PROCEEDING.*—At a separate pro-
2 ceeding to determine the amount of punitive damages
3 to be awarded under paragraph (1), the court shall
4 consider the following:

5 (A) *The severity of the harm caused by the*
6 *conduct of the defendant.*

7 (B) *The duration of the conduct or any con-*
8 *cealment of such conduct by the defendant.*

9 (C) *The profitability of the conduct of the*
10 *defendant.*

11 (D) *The number of products sold or medical*
12 *procedures rendered for compensation, as the*
13 *case may be, by the defendant of the kind caus-*
14 *ing the harm complained of by the claimant.*

15 (E) *The total deterrent effect of other dam-*
16 *ages and punishment imposed upon the defend-*
17 *ant as a result of the misconduct, including com-*
18 *pensatory, exemplary and punitive damage*
19 *awards to individuals in situations similar to*
20 *those of the claimant and the severity of any*
21 *criminal or administrative penalties, or civil*
22 *finer, to which the defendant has been or may be*
23 *subjected.*

24 (3) *DETERMINATION.*—At the conclusion of a
25 separate proceeding under paragraph (1), the court

1 *shall determine the amount of punitive damages to be*
2 *awarded with respect to the health care liability ac-*
3 *tion involved and shall enter judgment for that*
4 *amount. The court shall clearly state its reasons for*
5 *setting the amount of such award in findings of fact*
6 *and conclusions of law, demonstrating consideration*
7 *of each of the factors described in paragraph (2).*

8 (d) *RESTRICTIONS PERMITTED.*—*Nothing in this Act*
9 *shall be construed to imply a right to seek punitive damages*
10 *where none exists under Federal or State law.*

11 **SEC. 106. PERIODIC PAYMENTS.**

12 *With respect to a health care liability action, if the*
13 *award of future damages exceeds \$100,000, the adjudicating*
14 *body shall, at the request of either party, enter a judgment*
15 *ordering that future damages be paid on a periodic basis*
16 *in accordance with the guidelines contained in the Uniform*
17 *Periodic Payments of Judgments Act, as promulgated by*
18 *the National Conference of Commissioners on Uniform*
19 *State Laws in July of 1990. The adjudicating body may*
20 *waive the requirements of this section if such body deter-*
21 *mines that such a waiver is in the interests of justice.*

22 **SEC. 107. SCOPE OF LIABILITY.**

23 (a) *IN GENERAL.*—*With respect to punitive and non-*
24 *economic damages, the liability of each defendant in a*
25 *health care liability action shall be several only and may*

1 *not be joint. Such a defendant shall be liable only for the*
 2 *amount of punitive or noneconomic damages allocated to*
 3 *the defendant in direct proportion to such defendant's per-*
 4 *centage of fault or responsibility for the injury suffered by*
 5 *the claimant.*

6 (b) *DETERMINATION OF PERCENTAGE OF LIABILITY.—*
 7 *With respect to punitive or noneconomic damages, the trier*
 8 *of fact in a health care liability action shall determine the*
 9 *extent of each party's fault or responsibility for injury suf-*
 10 *fered by the claimant, and shall assign a percentage of re-*
 11 *sponsibility for such injury to each such party.*

12 **SEC. 108. MANDATORY OFFSETS FOR DAMAGES PAID BY A**
 13 **COLLATERAL SOURCE.**

14 (a) *IN GENERAL.—With respect to a health care liabil-*
 15 *ity action, the total amount of damages received by an indi-*
 16 *vidual under such action shall be reduced, in accordance*
 17 *with subsection (b), by any other payment that has been,*
 18 *or will be, made to an individual to compensate such indi-*
 19 *vidual for the injury that was the subject of such action.*

20 (b) *AMOUNT OF REDUCTION.—The amount by which*
 21 *an award of damages to an individual for an injury shall*
 22 *be reduced under subsection (a) shall be—*

23 (1) *the total amount of any payments (other*
 24 *than such award) that have been made or that will*
 25 *be made to such individual to pay costs of or com-*

1 *pensate such individual for the injury that was the*
 2 *subject of the action; minus*

3 (2) *the amount paid by such individual (or by*
 4 *the spouse, parent, or legal guardian of such individ-*
 5 *ual) to secure the payments described in paragraph*
 6 (1).

7 (c) *DETERMINATION OF AMOUNTS FROM COLLATERAL*
 8 *SERVICES.—The reductions required under subsection (b)*
 9 *shall be determined by the court in a pretrial proceeding.*
 10 *At the subsequent trial—*

11 (1) *no evidence shall be admitted as to the*
 12 *amount of any charge, payments, or damage for*
 13 *which a claimant—*

14 (A) *has received payment from a collateral*
 15 *source or the obligation for which has been as-*
 16 *sured by a third party; or*

17 (B) *is, or with reasonable certainty, will be*
 18 *eligible to receive payment from a collateral*
 19 *source of the obligation which will, with reason-*
 20 *able certainty be assumed by a third party; and*

21 (2) *the jury, if any, shall be advised that—*

22 (A) *except for damages as to which the*
 23 *court permits the introduction of evidence, the*
 24 *claimant's medical expenses and lost income*

1 *have been or will be paid by a collateral source*
 2 *or third party; and*

3 *(B) the claimant shall receive no award for*
 4 *any damages that have been or will be paid by*
 5 *a collateral source or third party.*

6 **SEC. 109. TREATMENT OF ATTORNEYS' FEES AND OTHER**
 7 **COSTS.**

8 *(a) LIMITATION ON AMOUNT OF CONTINGENCY*
 9 *FEES.—*

10 *(1) IN GENERAL.—An attorney who represents,*
 11 *on a contingency fee basis, a claimant in a health*
 12 *care liability action may not charge, demand, receive,*
 13 *or collect for services rendered in connection with such*
 14 *action in excess of the following amount recovered by*
 15 *judgment or settlement under such action:*

16 *(A) 33⅓ percent of the first \$150,000 (or*
 17 *portion thereof) recovered, based on after-tax re-*
 18 *covery, plus*

19 *(B) 25 percent of any amount in excess of*
 20 *\$150,000 recovered, based on after-tax recovery.*

21 *(2) CALCULATION OF PERIODIC PAYMENTS.—In*
 22 *the event that a judgment or settlement includes peri-*
 23 *odic or future payments of damages, the amount re-*
 24 *covered for purposes of computing the limitation on*
 25 *the contingency fee under paragraph (1) shall be*

1 *based on the cost of the annuity or trust established*
 2 *to make the payments. In any case in which an an-*
 3 *nuity or trust is not established to make such pay-*
 4 *ments, such amount shall be based on the present*
 5 *value of the payments.*

6 **(b) CONTINGENCY FEE DEFINED.**—*As used in this sec-*
 7 *tion, the term “contingency fee” means any fee for profes-*
 8 *sional legal services which is, in whole or in part, contin-*
 9 *gent upon the recovery of any amount of damages, whether*
 10 *through judgment or settlement.*

11 **SEC. 110. STATE-BASED ALTERNATIVE DISPUTE RESOLU-**
 12 **TION MECHANISMS.**

13 **(a) ESTABLISHMENT BY STATES.**—*Each State is en-*
 14 *couraged to establish or maintain alternative dispute reso-*
 15 *lution mechanisms that promote the resolution of health*
 16 *care liability claims in a manner that—*

17 *(1) is affordable for the parties involved in the*
 18 *claims;*

19 *(2) provides for the timely resolution of claims;*
 20 *and*

21 *(3) provides the parties with convenient access to*
 22 *the dispute resolution process.*

23 **(b) GUIDELINES.**—*The Attorney General, in consulta-*
 24 *tion with the Secretary and the Administrative Conference*
 25 *of the United States, shall develop guidelines with respect*

1 *to alternative dispute resolution mechanisms that may be*
 2 *established by States for the resolution of health care liabil-*
 3 *ity claims. Such guidelines shall include procedures with*
 4 *respect to the following methods of alternative dispute reso-*
 5 *lution:*

6 (1) *ARBITRATION.—The use of arbitration, a*
 7 *nonjury adversarial dispute resolution process which*
 8 *may, subject to subsection (c), result in a final deci-*
 9 *sion as to facts, law, liability or damages. The parties*
 10 *may elect binding arbitration.*

11 (2) *MEDIATION.—The use of mediation, a settle-*
 12 *ment process coordinated by a neutral third party*
 13 *without the ultimate rendering of a formal opinion as*
 14 *to factual or legal findings.*

15 (3) *EARLY NEUTRAL EVALUATION.—The use of*
 16 *early neutral evaluation, in which the parties make*
 17 *a presentation to a neutral attorney or other neutral*
 18 *evaluator for an assessment of the merits, to encour-*
 19 *age settlement. If the parties do not settle as a result*
 20 *of assessment and proceed to trial, the neutral eval-*
 21 *uator's opinion shall be kept confidential.*

22 (4) *EARLY OFFER AND RECOVERY MECHANISM.—*
 23 *The use of early offer and recovery mechanisms under*
 24 *which a health care provider, health care organiza-*
 25 *tion, or any other alleged responsible defendant may*

1 *offer to compensate a claimant for his or her reason-*
2 *able economic damages, including future economic*
3 *damages, less amounts available from collateral*
4 *sources.*

5 (5) *CERTIFICATE OF MERIT.*—*The requirement*
6 *that a claimant in a health care liability action sub-*
7 *mit to the court before trial a written report by a*
8 *qualified specialist that includes the specialist's deter-*
9 *mination that, after a review of the available medical*
10 *record and other relevant material, there is a reason-*
11 *able and meritorious cause for the filing of the action*
12 *against the defendant.*

13 (6) *NO FAULT.*—*The use of a no-fault statute*
14 *under which certain health care liability actions are*
15 *barred and claimants are compensated for injuries*
16 *through their health plans or through other appro-*
17 *priate mechanisms.*

18 (c) *FURTHER REDRESS.*—

19 (1) *IN GENERAL.*—*The extent to which any*
20 *party may seek further redress (subsequent to a deci-*
21 *sion of an alternative dispute resolution method) con-*
22 *cerning a health care liability claim in a Federal or*
23 *State court shall be dependent upon the methods of al-*
24 *ternative dispute resolution adopted by the State.*

1 (2) *CLAIMANT.*—With respect to further redress
2 described in paragraph (1), if the party initiating
3 such court action is the claimant and the claimant
4 receives a level of damages that is at least 25 percent
5 less under the decision of the court than under the
6 State alternative dispute resolution method, such
7 party shall bear the reasonable costs, including legal
8 fees, incurred in the court action by the other party
9 or parties to such action.

10 (3) *PROVIDER OR OTHER DEFENDANT.*—With re-
11 spect to further redress described in paragraph (1), if
12 the party initiating a court action is the health care
13 professional, health care provider health plan, or
14 other defendant in a health care liability action and
15 the health care professional, health care provider,
16 health plan or other defendant is found liable for a
17 level of damages that is at least 25 percent more
18 under the decision of the court than under the State
19 alternative dispute resolution method, such party
20 shall bear the reasonable costs, including legal fees,
21 incurred in the court action by the other party or
22 parties to such action.

23 (d) *TECHNICAL ASSISTANCE AND EVALUATIONS.*—

24 (1) *TECHNICAL ASSISTANCE.*—The Attorney
25 General may provide States with technical assistance

1 *in establishing or maintaining alternative dispute*
 2 *resolution mechanisms under this section.*

3 (2) *EVALUATIONS.*—*The Attorney General, in*
 4 *consultation with the Secretary and the Administra-*
 5 *tive Conference of the United States, shall monitor*
 6 *and evaluate the effectiveness of State alternative dis-*
 7 *pute resolution mechanisms established or maintained*
 8 *under this section.*

9 ***Subtitle B—Biomaterials Access***
 10 ***Assurance***

11 ***SEC. 121. SHORT TITLE.***

12 *This subtitle may be cited as the “Biomaterials Access*
 13 *Assurance Act of 1995”.*

14 ***SEC. 122. FINDINGS.***

15 *Congress finds that—*

16 (1) *each year millions of citizens of the United*
 17 *States depend on the availability of lifesaving or life-*
 18 *enhancing medical devices, many of which are perma-*
 19 *nently implantable within the human body;*

20 (2) *a continued supply of raw materials and*
 21 *component parts is necessary for the invention, devel-*
 22 *opment, improvement, and maintenance of the supply*
 23 *of the devices;*

24 (3) *most of the medical devices are made with*
 25 *raw materials and component parts that—*

1 (A) are not designed or manufactured spe-
2 cifically for use in medical devices; and

3 (B) come in contact with internal human
4 tissue;

5 (4) the raw materials and component parts also
6 are used in a variety of nonmedical products;

7 (5) because small quantities of the raw materials
8 and component parts are used for medical devices,
9 sales of raw materials and component parts for medi-
10 cal devices constitute an extremely small portion of
11 the overall market for the raw materials and medical
12 devices;

13 (6) under the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 301 et seq.), manufacturers of medical
15 devices are required to demonstrate that the medical
16 devices are safe and effective, including demonstrating
17 that the products are properly designed and have ade-
18 quate warnings or instructions;

19 (7) notwithstanding the fact that raw materials
20 and component parts suppliers do not design,
21 produce, or test a final medical device, the suppliers
22 have been the subject of actions alleging inadequate—

23 (A) design and testing of medical devices
24 manufactured with materials or parts supplied
25 by the suppliers; or

1 (B) warnings related to the use of such med-
2 ical devices;

3 (8) even though suppliers of raw materials and
4 component parts have very rarely been held liable in
5 such actions, such suppliers have ceased supplying
6 certain raw materials and component parts for use in
7 medical devices because the costs associated with liti-
8 gation in order to ensure a favorable judgment for the
9 suppliers far exceeds the total potential sales revenues
10 from sales by such suppliers to the medical device in-
11 dustry;

12 (9) unless alternate sources of supply can be
13 found, the unavailability of raw materials and com-
14 ponent parts for medical devices will lead to unavail-
15 ability of lifesaving and life-enhancing medical de-
16 vices;

17 (10) because other suppliers of the raw materials
18 and component parts in foreign nations are refusing
19 to sell raw materials or component parts for use in
20 manufacturing certain medical devices in the United
21 States, the prospects for development of new sources of
22 supply for the full range of threatened raw materials
23 and component parts for medical devices are remote;

24 (11) it is unlikely that the small market for such
25 raw materials and component parts in the United

1 *States could support the large investment needed to*
2 *develop new suppliers of such raw materials and com-*
3 *ponent parts;*

4 *(12) attempts to develop such new suppliers*
5 *would raise the cost of medical devices;*

6 *(13) courts that have considered the duties of the*
7 *suppliers of the raw materials and component parts*
8 *have generally found that the suppliers do not have*
9 *a duty—*

10 *(A) to evaluate the safety and efficacy of the*
11 *use of a raw material or component part in a*
12 *medical device; and*

13 *(B) to warn consumers concerning the safe-*
14 *ty and effectiveness of a medical device;*

15 *(14) attempts to impose the duties referred to in*
16 *subparagraphs (A) and (B) of paragraph (13) on*
17 *suppliers of the raw materials and component parts*
18 *would cause more harm than good by driving the sup-*
19 *pliers to cease supplying manufacturers of medical*
20 *devices; and*

21 *(15) in order to safeguard the availability of a*
22 *wide variety of lifesaving and life-enhancing medical*
23 *devices, immediate action is needed—*

1 (A) to clarify the permissible bases of liability
 2 for suppliers of raw materials and component
 3 parts for medical devices; and

4 (B) to provide expeditious procedures to dispose
 5 of unwarranted suits against the suppliers
 6 in such manner as to minimize litigation costs.

7 **SEC. 123. DEFINITIONS.**

8 As used in this subtitle:

9 (1) *BIOMATERIALS SUPPLIER.*—

10 (A) *IN GENERAL.*—The term “biomaterials
 11 supplier” means an entity that directly or indirectly
 12 supplies a component part or raw material
 13 for use in the manufacture of an implant.

14 (B) *PERSONS INCLUDED.*—Such term includes
 15 any person who—

16 (i) has submitted master files to the
 17 Secretary for purposes of premarket approval
 18 of a medical device; or

19 (ii) licenses a biomaterials supplier to
 20 produce component parts or raw materials.

21 (2) *CLAIMANT.*—

22 (A) *IN GENERAL.*—The term “claimant”
 23 means any person who brings a civil action, or
 24 on whose behalf a civil action is brought, arising
 25 from harm allegedly caused directly or indirectly

1 *by an implant, including a person other than*
 2 *the individual into whose body, or in contact*
 3 *with whose blood or tissue, the implant is placed,*
 4 *who claims to have suffered harm as a result of*
 5 *the implant.*

6 *(B) ACTION BROUGHT ON BEHALF OF AN*
 7 *ESTATE.—With respect to an action brought on*
 8 *behalf or through the estate of an individual into*
 9 *whose body, or in contact with whose blood or*
 10 *tissue the implant is placed, such term includes*
 11 *the decedent that is the subject of the action.*

12 *(C) ACTION BROUGHT ON BEHALF OF A*
 13 *MINOR.—With respect to an action brought on*
 14 *behalf or through a minor, such term includes*
 15 *the parent or guardian of the minor.*

16 *(D) EXCLUSIONS.—Such term does not in-*
 17 *clude—*

18 *(i) a provider of professional services,*
 19 *in any case in which—*

20 *(I) the sale or use of an implant*
 21 *is incidental to the transaction; and*

22 *(II) the essence of the transaction*
 23 *is the furnishing of judgment, skill, or*
 24 *services; or*

1 (ii) a manufacturer, seller, or
2 biomaterials supplier.

3 (3) COMPONENT PART.—

4 (A) IN GENERAL.—The term “component
5 part” means a manufactured piece of an im-
6 plant.

7 (B) CERTAIN COMPONENTS.—Such term in-
8 cludes a manufactured piece of an implant
9 that—

10 (i) has significant nonimplant appli-
11 cations; and

12 (ii) alone, has no implant value or
13 purpose, but when combined with other
14 component parts and materials, constitutes
15 an implant.

16 (4) HARM.—

17 (A) IN GENERAL.—The term “harm”
18 means—

19 (i) any injury to or damage suffered
20 by an individual;

21 (ii) any illness, disease, or death of
22 that individual resulting from that injury
23 or damage; and

1 (iii) any loss to that individual or any
2 other individual resulting from that injury
3 or damage.

4 (B) *EXCLUSION.*—The term does not in-
5 clude any commercial loss or loss of or damage
6 to an implant.

7 (5) *IMPLANT.*—The term “implant” means—

8 (A) a medical device that is intended by the
9 manufacturer of the device—

10 (i) to be placed into a surgically or
11 naturally formed or existing cavity of the
12 body for a period of at least 30 days; or

13 (ii) to remain in contact with bodily
14 fluids or internal human tissue through a
15 surgically produced opening for a period of
16 less than 30 days; and

17 (B) suture materials used in implant proce-
18 dures.

19 (6) *MANUFACTURER.*—The term “manufacturer”
20 means any person who, with respect to an implant—

21 (A) is engaged in the manufacture, prepara-
22 tion, propagation, compounding, or processing
23 (as defined in section 510(a)(1) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C.
25 360(a)(1)) of the implant; and

1 (B) is required—

2 (i) to register with the Secretary pur-
3 suant to section 510 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 360)
5 and the regulations issued under such sec-
6 tion; and

7 (ii) to include the implant on a list of
8 devices filed with the Secretary pursuant to
9 section 510(j) of such Act (21 U.S.C. 360(j))
10 and the regulations issued under such sec-
11 tion.

12 (7) *MEDICAL DEVICE*.—The term “medical de-
13 vice” means a device, as defined in section 201(h) of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 321(h)).

16 (8) *QUALIFIED SPECIALIST*.—With respect to an
17 action, the term “qualified specialist” means a person
18 who is qualified by knowledge, skill, experience, train-
19 ing, or education in the specialty area that is the sub-
20 ject of the action.

21 (9) *RAW MATERIAL*.—The term “raw material”
22 means a substance or product that—

23 (A) has a generic use; and

24 (B) may be used in an application other
25 than an implant.

1 (10) *SECRETARY*.—The term “Secretary” means
2 the Secretary of Health and Human Services.

3 (11) *SELLER*.—

4 (A) *IN GENERAL*.—The term “seller” means
5 a person who, in the course of a business con-
6 ducted for that purpose, sells, distributes, leases,
7 packages, labels, or otherwise places an implant
8 in the stream of commerce.

9 (B) *EXCLUSIONS*.—The term does not in-
10 clude—

11 (i) a seller or lessor of real property;

12 (ii) a provider of professional services,
13 in any case in which the sale or use of an
14 implant is incidental to the transaction and
15 the essence of the transaction is the furnish-
16 ing of judgment, skill, or services; or

17 (iii) any person who acts in only a fi-
18 nancial capacity with respect to the sale of
19 an implant.

20 **SEC. 124. GENERAL REQUIREMENTS; APPLICABILITY; PRE-**
21 **EMPTION.**

22 (a) *GENERAL REQUIREMENTS*.—

23 (1) *IN GENERAL*.—In any civil action covered by
24 this subtitle, a biomaterials supplier may raise any
25 defense set forth in section 125.

1 (2) *PROCEDURES.*—Notwithstanding any other
 2 provision of law, the Federal or State court in which
 3 a civil action covered by this subtitle is pending shall,
 4 in connection with a motion for dismissal or judg-
 5 ment based on a defense described in paragraph (1),
 6 use the procedures set forth in section 126.

7 (b) *APPLICABILITY.*—

8 (1) *IN GENERAL.*—Except as provided in para-
 9 graph (2), notwithstanding any other provision of
 10 law, this subtitle applies to any civil action brought
 11 by a claimant, whether in a Federal or State court,
 12 against a manufacturer, seller, or biomaterials sup-
 13 plier, on the basis of any legal theory, for harm alleg-
 14 edly caused by an implant.

15 (2) *EXCLUSION.*—A civil action brought by a
 16 purchaser of a medical device for use in providing
 17 professional services against a manufacturer, seller, or
 18 biomaterials supplier for loss or damage to an im-
 19 plant or for commercial loss to the purchaser—

20 (A) shall not be considered an action that
 21 is subject to this subtitle; and

22 (B) shall be governed by applicable commer-
 23 cial or contract law.

24 (c) *SCOPE OF PREEMPTION.*—

1 (1) *IN GENERAL.*—*This subtitle supersedes any*
 2 *State law regarding recovery for harm caused by an*
 3 *implant and any rule of procedure applicable to a*
 4 *civil action to recover damages for such harm only to*
 5 *the extent that this subtitle establishes a rule of law*
 6 *applicable to the recovery of such damages.*

7 (2) *APPLICABILITY OF OTHER LAWS.*—*Any issue*
 8 *that arises under this subtitle and that is not gov-*
 9 *erned by a rule of law applicable to the recovery of*
 10 *damages described in paragraph (1) shall be governed*
 11 *by applicable Federal or State law.*

12 (d) *STATUTORY CONSTRUCTION.*—*Nothing in this sub-*
 13 *title may be construed—*

14 (1) *to affect any defense available to a defendant*
 15 *under any other provisions of Federal or State law in*
 16 *an action alleging harm caused by an implant; or*

17 (2) *to create a cause of action or Federal court*
 18 *jurisdiction pursuant to section 1331 or 1337 of title*
 19 *28, United States Code, that otherwise would not exist*
 20 *under applicable Federal or State law.*

21 **SEC. 125. LIABILITY OF BIOMATERIALS SUPPLIERS.**

22 (a) *IN GENERAL.*—

23 (1) *EXCLUSION FROM LIABILITY.*—*Except as*
 24 *provided in paragraph (2), a biomaterials supplier*

1 *shall not be liable for harm to a claimant caused by*
 2 *an implant.*

3 (2) *LIABILITY.*—*A biomaterials supplier that—*

4 (A) *is a manufacturer may be liable for*
 5 *harm to a claimant described in subsection (b);*

6 (B) *is a seller may be liable for harm to a*
 7 *claimant described in subsection (c); and*

8 (C) *furnishes raw materials or component*
 9 *parts that fail to meet applicable contractual re-*
 10 *quirements or specifications may be liable for a*
 11 *harm to a claimant described in subsection (d).*

12 (b) *LIABILITY AS MANUFACTURER.*—

13 (1) *IN GENERAL.*—*A biomaterials supplier may,*
 14 *to the extent required and permitted by any other ap-*
 15 *plicable law, be liable for harm to a claimant caused*
 16 *by an implant if the biomaterials supplier is the*
 17 *manufacturer of the implant.*

18 (2) *GROUND FOR LIABILITY.*—*The biomaterials*
 19 *supplier may be considered the manufacturer of the*
 20 *implant that allegedly caused harm to a claimant*
 21 *only if the biomaterials supplier—*

22 (A)(i) *has registered with the Secretary*
 23 *pursuant to section 510 of the Federal Food,*
 24 *Drug, and Cosmetic Act (21 U.S.C. 360) and the*
 25 *regulations issued under such section; and*

1 (ii) included the implant on a list of devices
 2 filed with the Secretary pursuant to section
 3 510(j) of such Act (21 U.S.C. 360(j)) and the
 4 regulations issued under such section; or

5 (B) is the subject of a declaration issued by
 6 the Secretary pursuant to paragraph (3) that
 7 states that the supplier, with respect to the im-
 8 plant that allegedly caused harm to the claim-
 9 ant, was required to—

10 (i) register with the Secretary under
 11 section 510 of such Act (21 U.S.C. 360),
 12 and the regulations issued under such sec-
 13 tion, but failed to do so; or

14 (ii) include the implant on a list of de-
 15 vices filed with the Secretary pursuant to
 16 section 510(j) of such Act (21 U.S.C. 360(j))
 17 and the regulations issued under such sec-
 18 tion, but failed to do so.

19 (3) ADMINISTRATIVE PROCEDURES.—

20 (A) IN GENERAL.—The Secretary may issue
 21 a declaration described in paragraph (2)(B) on
 22 the motion of the Secretary or on petition by
 23 any person, after providing—

24 (i) notice to the affected persons; and

1 (ii) an opportunity for an informal
2 hearing.

3 (B) *DOCKETING AND FINAL DECISION.*—Im-
4 mediately upon receipt of a petition filed pursu-
5 ant to this paragraph, the Secretary shall docket
6 the petition. Not later than 180 days after the
7 petition is filed, the Secretary shall issue a final
8 decision on the petition.

9 (C) *APPLICABILITY OF STATUTE OF LIMITA-*
10 *TIONS.*—Any applicable statute of limitations
11 shall toll during the period during which a
12 claimant has filed a petition with the Secretary
13 under this paragraph.

14 (c) *LIABILITY AS SELLER.*—A biomaterials supplier
15 may, to the extent required and permitted by any other ap-
16 plicable law, be liable as a seller for harm to a claimant
17 caused by an implant if the biomaterials supplier—

18 (1) held title to the implant that allegedly caused
19 harm to the claimant as a result of purchasing the
20 implant after—

21 (A) the manufacture of the implant; and

22 (B) the entrance of the implant in the
23 stream of commerce; and

24 (2) subsequently resold the implant.

1 (d) *LIABILITY FOR VIOLATING CONTRACTUAL RE-*
2 *QUIREMENTS OR SPECIFICATIONS.*—A biomaterials sup-
3 plier may, to the extent required and permitted by any
4 other applicable law, be liable for harm to a claimant
5 caused by an implant, if the claimant in an action shows,
6 by a preponderance of the evidence, that—

7 (1) *the raw materials or component parts deliv-*
8 *ered by the biomaterials supplier either—*

9 (A) *did not constitute the product described*
10 *in the contract between the biomaterials supplier*
11 *and the person who contracted for delivery of the*
12 *product; or*

13 (B) *failed to meet any specifications that*
14 *were—*

15 (i) *provided to the biomaterials sup-*
16 *plier and not expressly repudiated by the*
17 *biomaterials supplier prior to acceptance of*
18 *delivery of the raw materials or component*
19 *parts;*

20 (ii)(I) *published by the biomaterials*
21 *supplier;*

22 (II) *provided to the manufacturer by*
23 *the biomaterials supplier; or*

24 (III) *contained in a master file that*
25 *was submitted by the biomaterials supplier*

1 to the Secretary and that is currently main-
 2 tained by the biomaterials supplier for pur-
 3 poses of premarket approval of medical de-
 4 vices; or

5 (iii)(I) included in the submissions for
 6 purposes of premarket approval or review
 7 by the Secretary under section 510, 513,
 8 515, or 520 of the Federal Food, Drug, and
 9 Cosmetic Act (21 U.S.C. 360, 360c, 360e, or
 10 360j); and

11 (II) have received clearance from the
 12 Secretary,

13 if such specifications were provided by the man-
 14 ufacturer to the biomaterials supplier and were
 15 not expressly repudiated by the biomaterials sup-
 16 plier prior to the acceptance by the manufac-
 17 turer of delivery of the raw materials or compo-
 18 nent parts; and

19 (2) such conduct was an actual and proximate
 20 cause of the harm to the claimant.

21 **SEC. 126. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS**

22 **AGAINST BIOMATERIALS SUPPLIERS.**

23 (a) *MOTION TO DISMISS.*—In any action that is sub-
 24 ject to this subtitle, a biomaterials supplier who is a defend-
 25 ant in such action may, at any time during which a motion

1 *to dismiss may be filed under an applicable law, move to*
 2 *dismiss the action on the grounds that—*

3 *(1) the defendant is a biomaterials supplier; and*

4 *(2)(A) the defendant should not, for the purposes*
 5 *of—*

6 *(i) section 125(b), be considered to be a*
 7 *manufacturer of the implant that is subject to*
 8 *such section; or*

9 *(ii) section 125(c), be considered to be a*
 10 *seller of the implant that allegedly caused harm*
 11 *to the claimant; or*

12 *(B)(i) the claimant has failed to establish, pur-*
 13 *suant to section 125(d), that the supplier furnished*
 14 *raw materials or component parts in violation of con-*
 15 *tractual requirements or specifications; or*

16 *(ii) the claimant has failed to comply with the*
 17 *procedural requirements of subsection (b).*

18 *(b) PROCEDURAL REQUIREMENTS.—*

19 *(1) IN GENERAL.—The procedural requirements*
 20 *described in paragraphs (2) and (3) shall apply to*
 21 *any action by a claimant against a biomaterials sup-*
 22 *plier that is subject to this subtitle.*

23 *(2) MANUFACTURER OF IMPLANT SHALL BE*
 24 *NAMED A PARTY.—The claimant shall be required to*

1 *name the manufacturer of the implant as a party to*
2 *the action, unless—*

3 *(A) the manufacturer is subject to service of*
4 *process solely in a jurisdiction in which the*
5 *biomaterials supplier is not domiciled or subject*
6 *to a service of process; or*

7 *(B) an action against the manufacturer is*
8 *barred by applicable law.*

9 *(3) AFFIDAVIT.—At the time the claimant brings*
10 *an action against a biomaterials supplier the claim-*
11 *ant shall be required to submit an affidavit that—*

12 *(A) declares that the claimant has consulted*
13 *and reviewed the facts of the action with a quali-*
14 *fied specialist, whose qualifications the claimant*
15 *shall disclose;*

16 *(B) includes a written determination by a*
17 *qualified specialist that the raw materials or*
18 *component parts actually used in the manufac-*
19 *ture of the implant of the claimant were raw*
20 *materials or component parts described in sec-*
21 *tion 125(d)(1), together with a statement of the*
22 *basis for such a determination;*

23 *(C) includes a written determination by a*
24 *qualified specialist that, after a review of the*
25 *medical record and other relevant material, the*

1 *raw material or component part supplied by the*
 2 *biomaterials supplier and actually used in the*
 3 *manufacture of the implant was a cause of the*
 4 *harm alleged by claimant, together with a state-*
 5 *ment of the basis for the determination; and*

6 *(D) states that, on the basis of review and*
 7 *consultation of the qualified specialist, the claim-*
 8 *ant (or the attorney of the claimant) has con-*
 9 *cluded that there is a reasonable and meritorious*
 10 *cause for the filing of the action against the*
 11 *biomaterials supplier.*

12 *(c) PROCEEDING ON MOTION TO DISMISS.—The fol-*
 13 *lowing rules shall apply to any proceeding on a motion to*
 14 *dismiss filed under this section:*

15 *(1) AFFIDAVITS RELATING TO LISTING AND DEC-*
 16 *LARATIONS.—*

17 *(A) IN GENERAL.—The defendant in the ac-*
 18 *tion may submit an affidavit demonstrating that*
 19 *defendant has not included the implant on a list,*
 20 *if any, filed with the Secretary pursuant to sec-*
 21 *tion 510(j) of the Federal Food, Drug, and Cos-*
 22 *metic Act (21 U.S.C. 360(j)).*

23 *(B) RESPONSE TO MOTION TO DISMISS.—In*
 24 *response to the motion to dismiss, the claimant*
 25 *may submit an affidavit demonstrating that—*

1 (i) the Secretary has, with respect to
 2 the defendant and the implant that alleg-
 3 edly caused harm to the claimant, issued a
 4 declaration pursuant to section
 5 125(b)(2)(B); or

6 (ii) the defendant who filed the motion
 7 to dismiss is a seller of the implant who is
 8 liable under section 125(c).

9 (2) *EFFECT OF MOTION TO DISMISS ON DISCOV-*
 10 *ERY.—*

11 (A) *IN GENERAL.—*If a defendant files a
 12 motion to dismiss under paragraph (1) or (3) of
 13 subsection (a), no discovery shall be permitted in
 14 connection to the action that is the subject of the
 15 motion, other than discovery necessary to deter-
 16 mine a motion to dismiss for lack of jurisdiction,
 17 until such time as the court rules on the motion
 18 to dismiss in accordance with the affidavits sub-
 19 mitted by the parties in accordance with this
 20 section.

21 (B) *DISCOVERY.—*If a defendant files a mo-
 22 tion to dismiss under subsection (a)(2) on the
 23 grounds that the biomaterials supplier did not
 24 furnish raw materials or component parts in
 25 violation of contractual requirements or speci-

1 *fications, the court may permit discovery, as or-*
 2 *dered by the court. The discovery conducted pur-*
 3 *suant to this subparagraph shall be limited to is-*
 4 *ssues that are directly relevant to—*

5 *(i) the pending motion to dismiss; or*

6 *(ii) the jurisdiction of the court.*

7 *(3) AFFIDAVITS RELATING STATUS OF DEFEND-*
 8 *ANT.—*

9 *(A) IN GENERAL.—Except as provided in*
 10 *clauses (i) and (ii) of subparagraph (B), the*
 11 *court shall consider a defendant to be a*
 12 *biomaterials supplier who is not subject to an*
 13 *action for harm to a claimant caused by an im-*
 14 *plant, other than an action relating to liability*
 15 *for a violation of contractual requirements or*
 16 *specifications described in subsection (d).*

17 *(B) RESPONSES TO MOTION TO DISMISS.—*
 18 *The court shall grant a motion to dismiss any*
 19 *action that asserts liability of the defendant*
 20 *under subsection (b) or (c) of section 125 on the*
 21 *grounds that the defendant is not a manufac-*
 22 *turer subject to such subsection 125(b) or seller*
 23 *subject to subsection 125(c), unless the claimant*
 24 *submits a valid affidavit that demonstrates*
 25 *that—*

1 (i) with respect to a motion to dismiss
 2 contending the defendant is not a manufac-
 3 turer, the defendant meets the applicable re-
 4 quirements for liability as a manufacturer
 5 under section 125(b); or

6 (ii) with respect to a motion to dismiss
 7 contending that the defendant is not a sell-
 8 er, the defendant meets the applicable re-
 9 quirements for liability as a seller under
 10 section 125(c).

11 (4) BASIS OF RULING ON MOTION TO DISMISS.—

12 (A) IN GENERAL.—The court shall rule on
 13 a motion to dismiss filed under subsection (a)
 14 solely on the basis of the pleadings of the parties
 15 made pursuant to this section and any affidavits
 16 submitted by the parties pursuant to this section.

17 (B) MOTION FOR SUMMARY JUDGMENT.—
 18 Notwithstanding any other provision of law, if
 19 the court determines that the pleadings and affi-
 20 davits made by parties pursuant to this section
 21 raise genuine issues as concerning material facts
 22 with respect to a motion concerning contractual
 23 requirements and specifications, the court may
 24 deem the motion to dismiss to be a motion for

1 *summary judgment made pursuant to subsection*
2 *(d).*

3 *(d) SUMMARY JUDGMENT.—*

4 *(1) IN GENERAL.—*

5 *(A) BASIS FOR ENTRY OF JUDGMENT.—A*
6 *biomaterials supplier shall be entitled to entry of*
7 *judgment without trial if the court finds there is*
8 *no genuine issue as concerning any material fact*
9 *for each applicable element set forth in para-*
10 *graphs (1) and (2) of section 125(d).*

11 *(B) ISSUES OF MATERIAL FACT.—With re-*
12 *spect to a finding made under subparagraph (A),*
13 *the court shall consider a genuine issue of mate-*
14 *rial fact to exist only if the evidence submitted*
15 *by claimant would be sufficient to allow a rea-*
16 *sonable jury to reach a verdict for the claimant*
17 *if the jury found the evidence to be credible.*

18 *(2) DISCOVERY MADE PRIOR TO A RULING ON A*
19 *MOTION FOR SUMMARY JUDGMENT.—If, under appli-*
20 *cable rules, the court permits discovery prior to a rul-*
21 *ing on a motion for summary judgment made pursu-*
22 *ant to this subsection, such discovery shall be limited*
23 *solely to establishing whether a genuine issue of mate-*
24 *rial fact exists.*

1 (3) *DISCOVERY WITH RESPECT TO A*
2 *BIOMATERIALS SUPPLIER.*—A biomaterials supplier
3 shall be subject to discovery in connection with a mo-
4 tion seeking dismissal or summary judgment on the
5 basis of the inapplicability of section 125(d) or the
6 failure to establish the applicable elements of section
7 125(d) solely to the extent permitted by the applicable
8 Federal or State rules for discovery against
9 nonparties.

10 (e) *STAY PENDING PETITION FOR DECLARATION.*—If
11 a claimant has filed a petition for a declaration pursuant
12 to section 125(b) with respect to a defendant, and the Sec-
13 retary has not issued a final decision on the petition, the
14 court shall stay all proceedings with respect to that defend-
15 ant until such time as the Secretary has issued a final deci-
16 sion on the petition.

17 (f) *MANUFACTURER CONDUCT OF PROCEEDING.*—The
18 manufacturer of an implant that is the subject of an action
19 covered under this subtitle shall be permitted to file and
20 conduct a proceeding on any motion for summary judgment
21 or dismissal filed by a biomaterials supplier who is a de-
22 fendant under this section if the manufacturer and any
23 other defendant in such action enter into a valid and appli-
24 cable contractual agreement under which the manufacturer

1 *agrees to bear the cost of such proceeding or to conduct such*
 2 *proceeding.*

3 (g) *ATTORNEY FEES.*—*The court shall require the*
 4 *claimant to compensate the biomaterials supplier (or a*
 5 *manufacturer appearing in lieu of a supplier pursuant to*
 6 *subsection (f)) for attorney fees and costs, if—*

7 (1) *the claimant named or joined the*
 8 *biomaterials supplier; and*

9 (2) *the court found the claim against the*
 10 *biomaterials supplier to be without merit and frivo-*
 11 *lous.*

12 ***Subtitle C—Applicability***

13 ***SEC. 131. APPLICABILITY.***

14 *This title shall apply to all civil actions covered under*
 15 *this title that are commenced on or after the date of enact-*
 16 *ment of this Act, including any such action with respect*
 17 *to which the harm asserted in the action or the conduct*
 18 *that caused the injury occurred before the date of enactment*
 19 *of this Act.*

1 **TITLE II—PROTECTION OF THE**
 2 **HEALTH AND SAFETY OF PA-**
 3 **TIENTS**

4 **SEC. 201. ADDITIONAL RESOURCES FOR STATE HEALTH**
 5 **CARE QUALITY ASSURANCE AND ACCESS AC-**
 6 **TIVITIES.**

7 *Each State shall require that not less than 50 percent*
 8 *of all awards of punitive damages resulting from all health*
 9 *care liability actions in that State, if punitive damages are*
 10 *otherwise permitted by applicable law, be used for activities*
 11 *relating to—*

12 *(1) the licensing, investigating, disciplining, and*
 13 *certification of health care professionals in the State;*
 14 *and*

15 *(2) the reduction of malpractice-related costs for*
 16 *health care providers volunteering to provide health*
 17 *care services in medically underserved areas.*

18 **SEC. 202. QUALITY ASSURANCE, PATIENT SAFETY, AND**
 19 **CONSUMER INFORMATION.**

20 *(a) ADVISORY PANEL.—*

21 *(1) IN GENERAL.—Not later than 90 days after*
 22 *the date of enactment of this Act, the Administrator*
 23 *of the Agency for Health Care Policy and Research*
 24 *(hereafter referred to in this section as the “Adminis-*
 25 *trator”)* shall establish an advisory panel to coordi-

1 *nate and evaluate, methods, procedures, and data to*
2 *enhance the quality, safety, and effectiveness of health*
3 *care services provided to patients.*

4 (2) *PARTICIPATION.*—*In establishing the advi-*
5 *sory panel under paragraph (1), the Administrator*
6 *shall ensure that members of the panel include rep-*
7 *resentatives of public and private sector entities hav-*
8 *ing expertise in quality assurance, risk assessment,*
9 *risk management, patient safety, and patient satisfac-*
10 *tion.*

11 (3) *OBJECTIVES.*—*In carrying out the duties de-*
12 *scribed in this section, the Administrator, acting*
13 *through the advisory panel established under para-*
14 *graph (1), shall conduct a survey of public and pri-*
15 *vate entities involved in quality assurance, risk as-*
16 *essment, patient safety, patient satisfaction, and*
17 *practitioner licensing. Such survey shall include the*
18 *gathering of data with respect to—*

19 (A) *performance measures of quality for*
20 *health care providers and health plans;*

21 (B) *developments in survey methodology,*
22 *sampling, and audit methods;*

23 (C) *methods of medical practice and pat-*
24 *terns, and patient outcomes; and*

1 (D) *methods of disseminating information*
2 *concerning successful health care quality im-*
3 *provement programs, risk management and pa-*
4 *tient safety programs, practice guidelines, pa-*
5 *tient satisfaction, and practitioner licensing.*

6 (b) *GUIDELINES.*—*Not later than 2 years after the date*
7 *of enactment of this Act, the Administrator shall, in accord-*
8 *ance with chapter 5 of title 5, United States Code, establish*
9 *health care quality assurance, patient safety and consumer*
10 *information guidelines. Such guidelines shall be modified*
11 *periodically when determined appropriate by the Adminis-*
12 *trator. Such guidelines shall be advisory in nature and not*
13 *binding.*

14 (c) *REPORTS.*—

15 (1) *INITIAL REPORT.*—*Not later than 6 months*
16 *after the date of enactment of this Act, the Adminis-*
17 *trator shall prepare and submit to the Committee on*
18 *Labor and Human Resources of the Senate and the*
19 *Committee on Commerce of the House of Representa-*
20 *tives, a report that contains—*

21 (A) *data concerning the availability of in-*
22 *formation relating to risk management, quality*
23 *assessment, patient safety, and patient satisfac-*
24 *tion;*

1 (B) an estimation of the degree of consensus
 2 concerning the accuracy and content of the infor-
 3 mation available under subparagraph (A);

4 (C) a summary of the best practices used in
 5 the public and private sectors for disseminating
 6 information to consumers; and

7 (D) an evaluation of the National Practi-
 8 tioner Data Bank (as established under the
 9 Health Quality Improvement Act of 1986), for
 10 reliability and validity of the data and the effec-
 11 tiveness of the Data Bank in assisting hospitals
 12 and medical groups in overseeing the quality of
 13 practitioners.

14 (2) *INTERIM REPORT.*—Not later than 1 year
 15 after the date of enactment of this Act, the Adminis-
 16 trator shall prepare and submit to the Committees re-
 17 ferred to in paragraph (1) a report, based on the re-
 18 sults of the advisory panel survey conducted under
 19 subsection (a)(3), concerning—

20 (A) the consensus of indicators of patient
 21 safety and risk;

22 (B) an assessment of the consumer perspec-
 23 tive on health care quality that includes an ex-
 24 amination of—

1 (i) the information most often re-
2 quested by consumers;

3 (ii) the types of technical quality infor-
4 mation that consumers find compelling;

5 (iii) the amount of information that
6 consumers consider to be sufficient and the
7 amount of such information considered
8 overwhelming; and

9 (iv) the manner in which such infor-
10 mation should be presented;

11 and recommendations for increasing the aware-
12 ness of consumers concerning such information;

13 (C) proposed methods, building on existing
14 data gathering and dissemination systems, for
15 ensuring that such data is available and acces-
16 sible to consumers, employers, hospitals, and pa-
17 tients;

18 (D) the existence of legal, regulatory, and
19 practical obstacles to making such data available
20 and accessible to consumers;

21 (E) privacy or proprietary issues involving
22 the dissemination of such data;

23 (F) an assessment of the appropriateness of
24 collecting such data at the Federal or State level;

1 (G) an evaluation of the value of permitting
 2 consumers to have access to information con-
 3 tained in the National Practitioner Data Bank
 4 and recommendations to improve the reliability
 5 and validity of the information; and

6 (H) the reliability and validity of data col-
 7 lected by the State medical boards and rec-
 8 ommendations for developing investigation pro-
 9 tocols.

10 (3) ANNUAL REPORT.—Not later than 1 year
 11 after the date of the submission of the report under
 12 paragraph (2), and each year thereafter, the Adminis-
 13 trator shall prepare and submit to the Committees re-
 14 ferred to in paragraph (1) a report concerning the
 15 progress of the advisory panel in the development of
 16 a consensus with respect to the findings of the panel
 17 and in the development and modification of the
 18 guidelines required under subsection (b).

19 (4) TERMINATION.—The advisory panel shall ter-
 20 minate on the date that is 3 years after the date of
 21 enactment of this Act.

22 **TITLE III—SEVERABILITY**

23 **SEC. 301. SEVERABILITY.**

24 If any provision of this Act, an amendment made by
 25 this Act, or the application of such provision or amendment

1 *to any person or circumstance is held to be unconstitu-*
2 *tional, the remainder of this Act, the amendments made by*
3 *this Act, and the application of the provisions of such to*
4 *any person or circumstance shall not be affected thereby.*

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